Dorset County Hospital
NHS Foundation Trust

Policy Title	*DCH Review of clinical trials involving ATIMPS*		
Policy Number	**RES SOP 001**	**Policy Version Number**	1.0
Applicable to	*All staff who undertake or support research involving Advanced Therapy Investigational Medicinal Products (ATIMPS) at Dorset County Hospital*		
Aim of the Policy	*The purpose of this Standard Operating Procedure (SOP) is to explain the local application and review process of the DCH ATIMP committee.*		
Next Review Due Date	*Unless agreed otherwise, the review will be 3-yearly.*		
Author/ Reviewer	*Amy Thomson & Anthony Homer* *Research Governance Administrator & Quality and Governance Lead*		
Policy Sponsor	*Sarah Doyle Clinical Lead & Head of Research*		
Expert Group	*Sarah Doyle - Clinical Lead & Head of Research* *Jean Kilroy – Deputy Director of Pharmacy* *Jo Allison – Clinical Research Lead*		
Date Approved	*19th February 2026*		
Primary Specialty	*Research*		
Secondary Specialties	*All Departments (active in research)*		

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Content

1. Introduction

1.1 Scope

This SOP describes research's involvement in the use of ATIMPS at DCH. As part of 'out of scope' it will detail all other research which does not involve the use of the ATIMPs at DCH

1.2 Purpose

The purpose of this SOP is to explain the application and review process of the DCH ATIMP committee.

1.3 Responsibilities

Researchers who wish to undertake research at DCH involving ATIMPs are responsible for ensuring that approval is sought from the DCH ATIMP Committee prior to commencement the research, by completing the risk assessment form and submitting it to R&D as instructed. All other applicable approvals should also be completed such as Capacity and Capability.

DCH ATIMP committee are responsible for providing a detailed review of the ATIMP application in compliance with the committee's terms of reference.

Research and Delivery staff are responsible for providing advice to researchers on the process. On receipt of a completed risk assessment form R&D staff will submit this and all relevant supporting documents to the committee, facilitating any discussions with committee members as required and on receipt of the approval from the committee sharing that with the applicable researchers and updating the research management database.

1.4 Acronyms, Definitions and Descriptions

Acronyms	Definition	Description
ATIMP	Advanced Therapy Investigational Medicinal Product	An ATIMP as defined in Article 2(1) of Regulation 1394/2007 which is tested or used in a clinical trial (in accordance with Article 2(d) of Directive 2001/20/EC If any researchers are unclear whether their trial involves an ATIMP they must contact R&D within the research department as soon as possible on 01305 253127
C&C	Capacity and Capability	N/A
GM	Genetically Modified	N/A
GTAC	Gene Therapy Advisory Committee	N/A

GTMP	Gene Therapy Medicinal Product	Biological Medicinal Product with the following characteristics: - It contains an active substance which contains or consists of a recombinant nucleic acid used in or administered to human beings with a view to regulating, repairing, replacing, adding or deleting a genetic sequence. - Its therapeutic, prophylactic or diagnostic effect relates directly to the recombinant nucleic acid sequence it contains, or to the product of genetic expression of this sequence.
HRA	Health Research Authority	N/A
IMP	Investigational Medicinal Product	N/A
PI	Principle Investigator	N/A
R & D	Research and Delivery	N/A
RPM	Research Project Manager	N/A
SCTMP	Somatic Cell Therapy Medicinal Product	Somatic Cell Therapy Medicinal Products involve: - A substantial manipulation of cells or tissues not intended to be used for the same essential function/s: - Administration to human beings with a view to treating, preventing or diagnosing a disease through the pharmacological, immunological or metabolic action
TEP	Tissue Engineered Product	Tissue Engineered Products involve: - Engineered cells or tissues - Administration to human beings with view to regenerating, repairing or replacing a human tissue.

1.5 Related Documents

Policy for the Use of Advanced Therapy Investigational Medicinal Products – DCH Staffnet.

2. Legislation, Guidelines and References

Directive 2001/83/EC, amended by 2003/63/EC annex 1, Part 1 http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32003L0063

Directive 2001/20/EC http://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2001_20/dir_200 1_20_en.pdf

Regulation 1394/2007
https://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L2007:324:0121:0137:en@PDF

Statutory Instrument 1031: The Medicines for Human Use (Clinical Trials) Regulations 2004 https:// www.legislation.gov.uk/uksi/2004/1031/pdfs/uksi_20041031_en.pdf

The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 https://www.legislation.gov.uk/uksi/2019/744/contents/made?view=plain

3. Policy Content

3.1 Procedure

On receipt of a protocol confirming that the intended research will involve the use of ATIMPs the Principal Investigator should inform Pharmacy and in conjunction with members of the local research team, complete the applicable sections of the Feasibility form with particular respect towards preparatory requirements for the IMP. Once completed they should submit the application with the Protocol and any other supporting documents (R&D can advise on what is required, but as a minimum; the Protocol, Investigator Brochure, Contract & Costings template and IRAS form) to research@dchft.nhs.uk . The process should be supported by the Research Project Managers and clinical research delivery team.

Depending on the type of ATIMP and potential risk, the trial should then be submitted for either proportionate or full review by the DCH ATIMP committee.

3.2 Proportionate review

Proportionate review will be applied to research which meet the following criteria:

a) Involves an ATIMP which does not fall under the GM regulations (e.g. somatic cell therapy)
b) The level of perceived risk is low (e.g. ATIMP is stored and administered at another site)
c) The ATIMP committee have previously reviewed and approved a trial using the same ATIMP where all processes and handling of the product are the same

On receipt of the application and supporting documents the Research Project Manager (RPM) allocated to the study should submit the application to the Director of Research

who is Chair (option 1- stick with this or 2- delegate this authority) of the ATIMP committee, for consideration.

Where a new trial meets criterion (c) above, and all processes and handling of an ATIMP have been previously reviewed by the committee, a new ATIMP Feasibility form may not be required to be completed, upon agreement from the Director of Research. In this instance a copy of the approved ATIMP Feasibility form for the previous trial will be provided for information.

The Head of Research should review the paperwork and in consultation with Senior management, R&D and members of the ATIMP committee (as required) should agree whether it can go through proportionate review. If it is accepted for proportionate review the Director (Chair) should primarily conduct the review with consultation with members of the ATIMP committee as required. If approved the authorisation section on the application should be completed electronically and the authorised form sent back to the allocated RPM who in turn should send this to the PI and applicable research team. If a new ATIMP Feasibility form has not be completed, written agreement will be obtained via email from/ or on behalf of the Head of Research.

The RPM should then continue to liaise with the PI and research team in line with relevant SOPs within the Research Department at DCH to ensure C&C is provided.

3.3 Full review by the DCH ATIMP committee

For research not meeting any of the criteria set out in section 3.2 above, a full review by the DCH ATIMP committee is required.

On receipt of the application and supporting documents the RPM allocated to the study should submit the application to the members of the DCH ATIMP committee for consideration via email to the Chair.

Each committee member should review the application and add comments to the relevant section of the submitted form. Any queries raised by the committee should be returned to the RPM assigned to the study to discuss and obtain a response from the PI and applicable research staff. Once each committee members comments have been addressed, they should complete the relevant authorisation section on the application and return to the RPM. Authorisations will be collected electronically. Whilst there is no deadline for reviews, it is expected that each committee member should undertake the review in a timely manner with the individual trial timelines in mind.

In some instances, a meeting may be required of the core members of the ATIMP committee to discuss the application. This meeting should be convened in line with the committees Terms of Reference. Following this meeting any actions should be followed up by the RPM and the PI.

Once all sections have been authorised the application and associated study documents should be submitted by the RPM to the DCH ATIMP committee Chair for review and final sign-off before being returned to the RPM, who in turn should send this to the PI and applicable research team.

The RPM should then continue to liaise with the PI and research team in line with SOPs across the research department to ensure C&C is provided.

Exceptions:

- In some instances, it may not be feasible to follow the processes described above e.g. an expedited review is required due to an urgent public health need, such as during the COVID19 pandemic. The Chair of the Committee will discuss and agree the most appropriate proportionate approach with senior management at R&D and that process will be clearly documented.

4. Equality Impact Assessment

A short statement summarising the assessment sheet, the completed Equality Impact and Compliance Assessment (Ref 1772) for the policy, should be attached as Appendix A (a blank version has already been attached below for your use).

For more information, read the Equality Policy EM67 (Ref 1772)

5. Data Protection Impact Assessment

Please refer to the Data Protection and Confidentiality Policy (Ref 1751)

If the policy is exempt it should be documented here, otherwise read the Data Protection Impact Assessment (Ref1751) and complete the Data Protection Impact Assessment (DPIA) Screening Questionnaire (Ref 1751) and attach as Appendix B (a blank version has already been attached below for you).

The Information Governance Officer is happy to assist with the completion of the Screening Questionnaire if required. If a full DPIA is required, it should be completed in consultation with the Information Governance Officer and attached as appendix B.

6. Stakeholders and Consultation

- Head of Research Department DCH
- Research ATIMP Committee DCH
- Research Quality and Governance Manager

7. Dissemination

This SOP will be disseminated to applicable research staff (including R&D).

All staff whose activities are subject to this SOP should ensure that they read and understand the content of the SOP. The personal training log of the individual (and the Investigator Site File/ Trial Master Fille if required) should be completed to document that the content of this SOP has been read and understood as described in SOPs across the Research Department.

Training and Implementation

- New users must read and understand this SOP before carrying out this procedure.
- Existing users must read and understand the revisions section.
- All users must have undergone recent GCP training.
- Trust mandatory training must be completed prior to implementing this SOP into practice.

8. Monitoring and Reviewing Arrangements

To be reviewed every three years, unless agreed otherwise, in accordance with the Policy for the Management of Policies and Guidance (Ref 1126).

9. Policy Approval

The policy will be approved in accordance with the Policy for the Management of Policies and Guidance (Ref 1126) and Procedure for the Development of Policies (Ref 1909).

Appendix A

EQUALITY IMPACT AND COMPLIANCE ASSESSMENT

1. General	
Title of document	DCH Review of clinical trials involving ATIMPs
Purpose of document	To describe the application and review process of the DCH ATIMP committee
Intended scope	In scope: All research involving the use of ATIMPS at DCH Out of scope: All other research which does not involve the use of ATIMPs at DCH

2. Consultation	
Which groups/associations/bodies or individuals were consulted in the formulation of this document?	Circulated for review and comment to the Research Clinical Team, Research Project Management Team prior to review by the Research Quality Group.
What was the impact of any feedback on the document?	Feedback was considered and incorporated into the final document as appropriate.
Who was involved in the approval of the final document?	The Research Quality Group
Any other comments to record?	None

3. Equality Impact Assessment	
Does the document unfairly affect certain staff or groups of staff? If so, please state how this is justified.	No
What measures are proposed to address any inequity?	N/A
Can the document be made available in alternative format or in translation?	On request.

4. Compliance Assessment	
Does the document comply with relevant employment legislation? **Please specify.**	Yes

5. Document assessed by:	
Name	Anthony Homer
Post Title/ Position	Research Governance & Quality Lead
Date	19th February 2026

Appendix B

Data Protection Impact Assessment (DPIA) Screening Questionnaire

Project/Policy/Procedure Title: Per Page 1

Project Lead: Anthony Homer

Date: 19th February 2026

Question		Yes	No	Unsure	Comments
1	Are privacy-intrusive[1] technologies being used?		X		Generally, not in the delivery of this SOP, even if research studies processed according to this SOP may have them.
2	Are new and untested technologies being used?		X		
3	Are the purposes of data processing unclear?		X		
4	What is the lawful basis for processing data?		X		Outline in the General Data Protection Regulation (GDPR)
5	Are new or substantially different identification authentication requirements needed?		X		Participant's data is managed in accordance with the GDPR & Study Protocol requirements. In compliance with Good Clinical Practice (GCP).
6	Will there be a significant amount of new data about each person, or a significant change in the current data-holdings?		X		Data may be collected and held in accordance with the Study Protocol, GDPR & GCP requirements.
7	Will there be new data about a significant number of people?		X		
8	Will there be a new link of personal data with another data-holding?		X		

[1] Intrusion can come in the form of collection of excessive personal information, disclosure of personal information without consent and misuse of such information. It can include the collection of information through surveillance or monitoring of how people act in public or private spaces and through the monitoring of communications whether by post, phone or online and extends to monitoring the records of senders and recipients as well as the content of messages.

9	Are the data collection procedures new, changed, unclear or intrusive?		X		
10	Will there be a new or changed data quality process?		X		
11	Will there be new or changed data security arrangements?		X		
12	Are there new or changed data access or disclosure arrangements?		X		
13	Are there new or changed data retention arrangements?		X		Retention of data will be determined by the study protocol and GDPR Regulations.
14	Has any external data sharing been identified on the departments data flow map?		X		
15	Is the personal data likely to raise privacy concerns with the individuals? e.g. health records, criminal records		X		All personal data is anonymised or pseudo anonymised in accordance with the ethically approved research study protocol.
16	Is there any use of highly sensitive or biometric data? e.g. protected characteristics or finger print recognition		X		
17	Will personal data be disclosed to organisations or people who have not previously had access to the data?		X		Data may be collected and held on a study database in accordance with the study

18	Will data collection and processing result in automated decision making which will have a Xsignificant impact on the individuals concerned?		X		
19	Will individuals be compelled to provide information about themselves?		X		
20	Is there a contract or data sharing agreement in place with all third parties?		X		Refer to study Protocol and Contract agreements.

If you have answered 'Yes' or 'Unsure' to any of the above, please consult with the Information Governance and Data Protection Officer. You may need to complete the full DPIA.

If all answers are 'No' or the Information Governance and Data Protection Officer has been consulted and approves, this Screening Questionnaire can be signed off by the Project Lead and responsible Information Asset Owner.

Name	**Job Title**	**Date**
Anthony Homer	Research Governance & Quality Lead	19th February 2026