



Independent Review Panel Charter

INTRODUCTION

Providing Access to Patient Level Data

The mission of Vivli is to promote, coordinate, and facilitate scientific sharing and reuse of clinical research data through the creation and implementation of a sustainable global data-sharing enterprise. Vivli acts as a neutral broker between data contributor, data user and the wider data sharing community. Vivli has harmonized governance, policy and processes to facilitate data sharing for users and contributors. The Vivli platform includes an independent data repository, in-depth search engine and a cloud-based, secure analytics platform. The ultimate vision of Vivli is to advance human health through clinical research data sharing, thereby respecting and honoring the contributions of clinical research participants.

In order to ensure data are requested by qualified researchers and used in a scientific and responsible manner, an **Independent Review Panel (IRP)** has been set up to review the scientific merit of research proposals submitted through the platform, for members who choose to use the IRP. For these members, the IRP must decide whether a request is appropriate before access to the data can be provided. Vivli manages an independent Secretariat to ensure the panel is independent from Data contributors who request services of the IRP. The independent Secretariat manages the operation of the IRP and liaises with the IRP Chair to appoint members. Vivli takes the responsibility for payment and contracting for IRP members. This Panel Charter sets out the responsibilities of the IRP and the decision-making process.

Independent Review Panel Membership

The panel consists of a Chair and four members with a range of expertise, including statistics, conducting clinical trials, ethics, data governance and a lay perspective. The list of current members can be found on the Vivli website. Panel members will review research proposals in a personal capacity, with due care, skill, and ability in accordance with their individual expertise. The Chair will make the final decision.

REVIEW PROCESS

Applicants requesting access to data submit a research proposal using the Vivli platform. Vivli will complete initial administrative checks before passing the proposal to the Data Contributor(s) for “feasibility checks”. For those Data Contributors who engage the IRP, Vivli will then pass the request, together with any relevant information from the data contributor to the Secretariat who then sends it to the IRP for review.

Each panel member undertakes a high-level review of the research proposal and determines whether there is any reason to reject the proposal. This review must be completed within 30 days of the proposal being sent to the IRP (unless the Panel requires further information).

Following the review, the IRP Secretariat will inform the requestor and Data Contributor(s) of the IRP’s



decision and any conditions or recommendations. Where data are to be made available, the researcher must sign a Data Use Agreement and the Data Contributor will make anonymized data available. The outcome of all requests, together with the reason for any rejection, will be published on the Vivli website.

It should be noted that it has been agreed that some Data Contributor(s) may decline a request if it does not meet their data sharing criteria, which is outlined on [their Vivli member's page](#).

IRP review: assessment criteria

Panel members will undertake a high-level review to assess:

- the scientific rationale and relevance of the proposed research to medical science or patient care
- the ability of the proposed research plan (design, methods and analysis) to meet the scientific objectives
- the publication plan for the research
- the plain English summary is clear with sufficient detail to be understood by a non-specialist
- with the information provided, real or potential conflicts of interest that may impact the planning, conduct or interpretation of the research and proposals to manage these conflicts of interest
- qualifications and experience of the research team to conduct the proposed research.

IRP review: decision-making process

Each panel member makes one of three recommendations:

1. Approval to provide access to the requested data
2. Rejection but with advice to re-submit the research proposal to address specific aspects
3. Rejection of the research proposal

The panel can also request more information before making a recommendation. Where panel members recommendations differ, the panel should seek consensus through discussion, but the Chairman will make the final decision. Three members will constitute a quorum. The Data Contributors cannot influence individual panel members or overturn or change the decisions of the Panel.



GOVERNANCE AND ADMINISTRATION

- Vivli has put in place an agreement with each IRP member.
IRP members are paid for their time and expertise in reviewing proposals. Payments are on a per review basis, with an annual review to assess demand. Vivli administers fees on behalf of the Data Contributor(s). Data Contributor(s) will disclose all payments to IRP members.
- The IRP Secretariat will provide guidance on the IRP's role and all necessary support to the IRP members
- The panel will operate virtually on an ongoing basis but will have a meeting once a year.
- IRP members will initially be appointed for a three-year term. After three years, the membership will be updated on an as needed basis, to help ensure consistency and continuity.