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INTRODUCTION

PURPOSE

Linear Clinical Research Ltd (Linear) is committed to the highest standards of legal, ethical and moral behaviour, in line with our core values of Integrity and Excellence. Linear will not tolerate unethical or unlawful conduct.

This policy documents Linear's commitment to maintaining an environment in which relevant parties are able to report – without fear of retaliatory action – concerns about any serious instances of wrongdoing that they believe may be occurring at, or in the name of Linear. The Linear Board is responsible for oversight of this Policy and its implementation.

Further, implementation of a Whistleblower Policy is a legal requirement under the Corporations Act 2001 (Cth). This document is constituted in accordance with the relevant provisions; its existence, and compliance with the Policy, allows Linear to correctly discharge its obligations.

SCOPE

The protections available under this policy are only available where the discloser has reasonable grounds for believing their assertion. This policy is not intended to replace other reporting structures or grievance procedures such as those for dispute resolution, grievances, equal opportunity, discrimination, harassment or bullying.

This Policy primarily applies to the reporting of suspected serious wrongdoing at Linear.

Whistleblowing in relation to other entities

Note that Linear and its employees may *also* be “eligible whistleblowers” under the law in relation to Linear's related body corporate (the Harry Perkins Institute of Medical Research), and in relation to clients (sponsor companies); which may be covered by the law yet not required to implement a whistleblower policy.

In order to qualify for protection, disclosures would need to be made either directly to relevant recipients in the other entity or to a regulatory body. This is not within the scope of this Policy.

In this light, where wrongdoing in another company is identified, reporting of this should typically be internal (for example, to an eligible recipient for Linear) and legal advice sought on Linear's behalf prior to a disclosure being made.

ASSOCIATED / REFERENCE DOCUMENTS

ADM001: Human Resources Policy Manual

QAS001: Quality Incident and CAPA Management

ADS005: Handling Suspected Misconduct

Relevant legislation: Corporations Act 2001 (Cth), Taxation Administration Act 1953 (Cth)

Relevant legislation: Therapeutic Goods Act 1989 (Cth)

Australian Securities & Investment Commission (ASIC): asic.gov.au/about-asic/asic-investigations-and-enforcement/whistleblowing/how-asic-handles-whistleblower-reports/

Australian Taxation Office (ATO): www.ato.gov.au/general/gen/whistleblowers/

Australian Prudential Regulation Authority (APRA): www.apra.gov.au/become-a-whistleblower-and-make-a-public-interest-disclosure

OUTLINE

This policy sets out, in accordance with the legislation, information regarding “disclosures” (where an individual reports information regarding an instance of potential wrongdoing to another relevant party) that are considered to be protected. Specifically:

1. What is considered a protected disclosure
 - *From* whom the disclosure may originate
 - *To* whom the disclosure may be made
 - *What* constitutes a disclosable matter
2. How a disclosure may be made
3. How a disclosure will be dealt with by Linear
4. Protection and support that will be in place
 - For the person making the disclosure, and
 - For any person to whom a disclosure relates
5. How this policy will be made available to relevant parties

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ABBREVIATIONS AND DEFINITIONS

Term	Definition
ASIC	Australian Securities and Investment Commission
ATO	Australian Taxation Office
APRA	Australian Prudential Regulation Authority
CAPA	Corrective and Preventive Action
CEO	Chief Executive Officer
CFO	Chief Financial Officer
Cth	Commonwealth (in relation to Acts of Parliament)
EAP	Employee Assistance Program
HPIMR	Harry Perkins Institute of Medical Research (HPIMR is an associated Body Corporate of Linear)
Whistleblowing	The deliberate, voluntary disclosure of individual or organisational wrongdoing by a person who has or had privileged access to data, events or information about an actual, suspected or anticipated wrongdoing within or by an organisation that is within its ability to control.
Wrongdoing	Any conduct that is: dishonest; fraudulent; corrupt; illegal; unethical; potentially damaging to Linear, another employee or contractor; serious impropriety; and may include concealment of Wrongdoing.

SECTION 1. PROTECTED DISCLOSURES

Under the law, there are particular requirements for a disclosure to be “protected”, as follows.

1.1. Eligible Whistleblower: who can make a disclosure.

In relation to Linear, an individual may be an eligible whistleblower if they are, or have been:

- An officer (including board members)
- An employee, including management
- A supplier of goods and/or services (whether paid or unpaid)
 - This includes employees of a supplier
 - This is also taken to include volunteers
- An associate (as defined by the Corporations Act, which includes a director or secretary of a related body corporate such as the Harry Perkins Institute of Medical Research)

Regarding the above categories of individual, any of the following are also eligible whistleblowers:

- A relative of an individual
- A dependent of an individual, or dependent of such an individual’s spouse

1.2. Eligible Recipient: who can receive a disclosure.

Any of the following are “eligible recipients” (i.e., disclosure to these parties is protected, if it meets the other criteria for eligibility).

- Regulatory bodies:
 - Australian Securities and Investment Commission (ASIC)
 - Australian Taxation Office (ATO)
 - Australian Prudential Regulation Authority (APRA)
- Defined individuals:
 - Officers (including board members / directors) of Linear or of the Harry Perkins Institute of Medical Research [HPIMR].
 - Senior managers of Linear or of the Harry Perkins Institute of Medical Research:

In relation to Linear, these are the CEO, CFO, Associate Medical Director, and all named *Heads of Department (Clinical Operations, Corporate Operations, Project Delivery, Partnering, Cancer Trials, Quality Assurance and People Operations)*.

In relation to HPIMR, this is the *Research Support Executive*; refer to perkins.org.au.
 - An auditor, or member of an audit team conducting an audit of Linear.
 - **Note:** *this relates to financial audits rather than regulatory audits (internal or external). Details of the company’s current financial auditor (at time of preparation, Ernst and Young) may be found in Linear’s financial accounts at acnc.gov.au.*
 - Any other person authorised by Linear (not applicable at the time of preparation).
 - Legal practitioners, where the disclosure is for the purpose of obtaining legal advice or representation in relation to the whistleblowing process.

- In certain situations, parliamentarians or journalists (see Public Interest Disclosure below, under *Making a Disclosure*).

1.3. Disclosable Matters: what can be reported that is protected

The law states that the following by Linear or its officers or employees (and/or a related company, i.e. the Harry Perkins Institute of Medical Research) is considered disclosable:

“Disclosure of information if the discloser has reasonable grounds to suspect that the information concerns misconduct, or an improper state of affairs or circumstances”

As the legal definition is very broad by nature, the intent of the Policy is targeted towards matters of a serious nature, for example:

- Fraudulent behaviour
- Offering or accepting a bribe
- Theft, violence, criminal damage
- Financial irregularities
- Negligence, breach of trust, breach of duty
- Failure to comply with legal or regulatory obligations
- Data fabrication, falsification, wilful concealment of errors
- Engaging in or threatening detrimental conduct toward someone who has or may have made or is planning to make a disclosure under this Policy.

Additionally, some items are specified by the legislation as disclosable matters:

- Breaches of [particular laws](#) (such as the Corporations Act 2001 and the Australian Securities and Investment Commission Act 2001)
 - Any conduct that represents a danger to the public or the financial system.
 - Breaches of any other Commonwealth law that is punishable by imprisonment of 12 months or more.
 - Of relevance to Linear’s operations is the Therapeutic Goods Act 1989, sections [19B](#) and [21A\(12\)](#), which outline criminal offenses in relation to unapproved goods.
- **Note:** *Personal work-related grievances are specifically not covered as protected under the Act, unless the grievance concerns detrimental action related to the whistleblowing process (see “Relevant Protections” below).*

The process for handling personal work-related grievances is set out in Linear’s Human Resources Policy Manual (document ADM001).

1.4. Summary: Protected Disclosures

⚠ **All three** of the above criteria (eligible discloser; recipient; and matter) must be met for a disclosure to be considered protected under the law.

One ‘blanket’ protection does exist under the law (s. 1317AA[3] of the Act), which is disclosure to a **legal practitioner** for the purpose of obtaining advice or representation in relation to the Act’s whistleblower protections. This applies regardless of the eligibility of the discloser or matter.

SECTION 2. MAKING A DISCLOSURE

In general, all persons employed by or interacting with Linear are encouraged to identify and report any instances of suspected wrongdoing, or other deviations – in line with Linear’s values of *Integrity & Excellence*. Intentional breaches of Linear policies will not be tolerated.

2.1. Identifying issues

Firstly, where potential wrongdoing is identified it should be assessed:

- Is it a serious offence?
- Does it meet the definition of a disclosable matter?

⚠ If in doubt, legal advice should be sought.

- **Note:** disclosure for the purpose of seeking legal advice is protected too – and this is true even if the matter turns out not to be a “disclosable” one as per the legislation (see 1.4 above).

There are alternative pathways for dealing with minor issues or non-disclosable matters, including the Quality Incident & CAPA process (refer to document QAS001) and Personal Grievance process (refer to the Human Resources Policy Manual, ADM001).

Additionally, there are reporting pathways described in document ADS005 *Handling Suspected Misconduct*, whilst this is directed more toward scientific or academic misconduct, please note that such matters may also be disclosable and protected under this Whistleblower Policy.

2.2. Identifying an eligible recipient

To qualify for protection, the matter must be disclosed to an “eligible recipient” (listed in Section 1.2). Employees can use the Linear contact list to identify an appropriate person and contact details.

In addition, and for those who are not employees of Linear, disclosers can refer to the Linear website (linear.org.au) for information on Board Members and Senior Managers.

In the event the person making the disclosure cannot locate a phone number or email address, a disclosure can be made to an eligible recipient via post to *1st Floor, B Block, Hospital Avenue, Nedlands WA 6009* with the item addressed to the recipient and marked as “In Confidence”.

Internal reporting is preferred in the first instance, as company employees and officers are in a better position to assess the potential wrongdoing and initiate an investigation.

For regulatory bodies (ASIC, ATO, APRA) resources regarding reports are available at the links in the *Associated / Reference Documents* section above.

2.3. How to report

Disclosures may be made at any time, verbally or in writing to the identified recipient(s).

Disclosures may be made anonymously and still be protected; and anonymity can be maintained throughout the disclosure and investigation process.

It is recommended to keep copies of correspondence and/or documenting communication made. Refer to the *Records* section at the end of this document for further information.

2.4. What to include in the report

It is recommended to clearly state that a disclosure is being made under this Whistleblower Policy and that it is believed to be a protected disclosure. This will assist the recipient in treating it in a correct manner.

Reports should contain sufficient detail (dates, locations, people involved, etc.) regarding the alleged wrongdoing in order that this can be identified by the recipient and an investigation can be initiated, if appropriate. Some amount of evidence would be expected on which to base the claim (*“reasonable grounds to suspect” as per the law, quoted in section 1.3*). However, there does not have to be conclusive proof.

Reports should include some method for the recipient to contact the whistleblower for additional information. This can, as noted, still be anonymous – for example, by use of an unrelated email address.

Contact details may be omitted; however, this may limit the ability of the recipient to act on the disclosure (e.g., if clarification cannot be sought) and to update the whistleblower as to progress with any investigation.

2.5. Public interest and emergency disclosures

Public Interest Disclosures are effectively a “last resort” and are protected where a report has previously been made to a Commonwealth body (i.e., ASIC or APRA); the body has apparently failed to act; and the whistleblower has reason to believe that further disclosure is in the public interest.

When certain criteria are met, a further disclosure may be made to a member of Parliament (either Commonwealth, or State/Territory) or to a journalist.

Emergency Disclosures are similar except the information must relate to “a substantial and imminent danger to the health or safety or one or more persons, or to the natural environment”.

The specific requirements for each are outlined in [Section 1317AAD](#) of the Corporations Act.

Note that the Taxation Administration Act does not make provision for such disclosures.

⚠ Legal advice should be sought before making a Public Interest or Emergency Disclosure.

SECTION 3. HANDLING AND INVESTIGATION

3.1. Receipt and assessment

Upon receipt of a report, the recipient will make a preliminary assessment of the information, including its potential status as a protected disclosure (*if this is uncertain, then the disclosure should be treated as protected by default*) and any need for investigation and follow-up.

Acknowledgement of receipt of the disclosure, and the outcome of the preliminary assessment, will be provided to the whistleblower (where contact details are available) within a reasonable period of receipt, ideally within 7 calendar days.

The recipient must establish, at the outset, if the whistleblower wishes to remain anonymous, or if their details may be passed on to the designated investigation officer and/or made public.

The recipient should document the process and rationale, whilst also taking care to maintain the confidentiality of the whistleblower (e.g., removing identifying information from a written narrative).

3.2. Initiation of investigation

Should an investigation be required, the recipient will, in confidence, report the disclosure to a designated investigation officer. The current investigation officers are the:

- Chief Executive Officer, and
- Head of Quality Assurance

The identity of the whistleblower cannot be directly passed on without their consent (this consent should be documented, if applicable); and if any information that could potentially identify the whistleblower is passed on all reasonable steps must be taken to reduce the risk of identification.

Should one of the designated investigation officers be identified as involved in the alleged conduct, then disclosure should be made to the other.

Should both investigation officers be involved, then advice should be sought by the recipient from a legal practitioner and/or the relevant regulatory body.

3.3. Conduct of investigation

The designated investigation officer will be responsible for ensuring the proper conduct of the investigation, which may include appropriate instruction and oversight of a third party appointed to conduct an investigation. Relevant provisions of this Policy, and the law, continue to apply to third party investigators.

Investigations will be performed in the following manner:

- *Independently*: the investigation will not be conducted by a person who may be the subject of the investigation or has inappropriate links or connections (actual or perceived) to the person(s) or practice(s) under investigation.
- *Objectively*: with the intention of locating evidence that either substantiates or refutes the claims made by the whistleblower.
- *Fairly*: persons involved with the alleged conduct will be treated in accordance with the principles of natural justice and protected as set out in this Policy (section 4.3).

Activities may involve collection of relevant data and interviewing individuals such as material witnesses (if any) to the alleged conduct and the person(s) that are the subject of the allegations.

The interview process will generally be conducted as follows, regarding the subject of allegations:

- The person will be given notice of the meeting and what will be discussed at the meeting.
- The person will be given a reasonable opportunity to have a support person present at the meeting.
- At the meeting, the issue(s) of concern or allegations will be put to the person, including any evidence upon which those concerns or allegations are based.
- The person will be given an adequate opportunity to respond to the concerns or allegations.

Following conclusion of the investigative activities, as necessary, the leader of the investigation will generate a documented record including:

- a summary of the process that was undertaken;
- an inventory of the facts and information that was gathered and analysed;
- an evaluation of facts and information;
- investigation outcome (based on the evidence); and
- recommendations for further action.

If, following an investigation, the allegations are found not to be substantiated, then any documents relating to the investigation will be handled confidentiality, subject to disclosures to the appropriate members of management, as appropriate.

All investigative activities must be clearly documented, including the activity undertaken, and the outcome including any evidence uncovered (whether confirmatory or contrary to the allegations).

3.4. Communication of investigation and outcomes

The designated investigation officer will keep the whistleblower informed of the outcome of the investigation of his/her report; specifically, within one calendar month of the disclosure being received, the whistleblower should be informed of the progress of the investigation. Further progress updates are to be made as relevant, and when the investigation is completed, the whistleblower should be informed of the outcome.

Communication to the whistleblower will be subject to the considerations of privacy of those against whom the allegations have been made, in accordance with protections set out elsewhere in this document (section 4.3).

The Linear Board will also be informed of the initiation, progress and outcome of any investigation, subject to confidentiality of the whistleblower, as described in the following section, and operational considerations (e.g. should a Board member be the subject of an investigation).

SECTION 4. RELEVANT PROTECTIONS

This section outlines how, in relation to a “protected disclosure”, the protections actually function.

- **Note:** *protections also relate to ‘suspected’ whistleblowers, for example if the disclosure is anonymous, or if an individual is believed to have made or is planning to make a disclosure (without this being certain).*

4.1. How the law protects whistleblowers

This policy was written primarily with reference to Part 9.4AAA of the Corporations Act 2001 (Cth). However, it should also be noted that similar protections exist for taxation-related matters under Part IVD of the [Taxation Administration Act 1953 \(Cth\)](#). Further information on these matters can be obtained via the ATO.

4.1.1. Confidentiality

It is illegal for the identity of a whistleblower to be revealed except in the following circumstances:

- **With the consent of the whistleblower.**
- Where the disclosure is made to ASIC, APRA or the Australian Federal Police.
- Where the disclosure is made to a legal practitioner for the purpose of obtaining legal advice or representation in relation to the whistleblowing process (this would continue to be protected by lawyer-client confidentiality).

Further, any information that could reveal the whistleblower’s identity is protected in the same manner and can be disclosed under the same circumstances as above, e.g., **with consent**.

- **Note:** *potentially identifying information (but not the actual identity) **can** be disclosed where it is necessary to further an investigation, as long as all reasonable steps are taken to reduce the risks that the whistleblower will be identified.*

These protections apply to the suspected identity of a(n otherwise anonymous) whistleblower.

Disclosures can also be made anonymously (or using a pseudonym).

4.1.2. Protection from civil, criminal or administrative liability

Whistleblowers cannot be prosecuted, sued or subject to disciplinary action just for having made a disclosure [where this is protected] – even if, for example, it technically breaches a confidentiality agreement.

- **Note:** *this provision does not prevent action against a whistleblower for any involvement in improper conduct, that is revealed by way of making the disclosure.*

4.1.3. Protection from victimisation

Companies (i.e., Linear), their employees and officers, or related parties (e.g. HPIMR), are legally prevented from acting to the [detriment](#) (such as dismissal, harassment, discrimination, damaging reputation) of a whistleblower because they have made a disclosure – this is a criminal offence. Further, even threats (whether or not the person threatened actually fears that the threats will be carried out) are similarly prohibited.

As noted, this applies even if a person is *suspected* to have made a disclosure.

4.1.4. Availability of compensation

The law specifically allows for whistleblowers to seek compensation (or other remedies) through the courts if they suffer detriment as the result of a disclosure. This also applies if an individual suffers detriment and Linear fails to make adequate precautions to prevent the detrimental acts from occurring.

⚠ It is recommended that legal advice be sought before pursuing compensation.

4.2. How Linear protects and supports whistleblowers

Linear is committed to protecting and respecting the rights of whistleblowers, in accordance with the law and our core value of respect. Linear intends to create a safe environment in which concerns can be raised without fear of detriment.

Misconduct or other wrongdoing is taken seriously by Linear and when informed of concerns, we will assess or investigate these in good faith, in accordance with this Policy.

Linear and its officers and management are committed to maintaining the confidentiality of whistleblowers, and their wellbeing. Training is given to the relevant personnel so that they are aware of their obligations under this Policy and the law.

Linear will not tolerate any retaliatory action or threats of retaliatory action against any person who has made, or who is believed to have made a report of wrongdoing, or against that person's colleagues, employer (if a contractor) or relatives. Allegations of retaliatory action will be investigated under this Policy, and any person found to have done so will face disciplinary action, which may include dismissal, and the matter will be referred to the appropriate authorities for action.

Support is available to employees including the Employee Assistance Program (EAP), which provides a free counselling service to employees and their family members.

4.3. How Linear protects and supports subjects of allegations

It is important to note that those who are the subject of an allegation must be treated fairly and in accordance with the principles of natural justice, i.e., with the presumption of innocence. Any finding of wrongdoing must be based upon sufficient evidence gathered during a thorough and objective investigation process.

Where allegations are proven to be unfounded, Linear will make every effort to reinstate the reputation (where this has suffered harm) of the subject. However, confidentiality of the subject must be maintained to the extent possible during the investigation, to prevent reputational harm.

In contrast to Linear's serious treatment of legitimate concerns and reports, deliberate false reports (where allegations are known by the discloser to be untrue) are taken seriously and those who make such false reports will face disciplinary action.

As noted above, the Employee Assistance Program is available to all Linear employees and their family members.

SECTION 5. COMMUNICATION OF THIS POLICY

This Policy will be made available or communicated to relevant parties via the following avenues.

For employees:

- Training to communicate the existence of the Policy and a summary of its provisions:
 - For new employees, during the induction process.
 - For existing employees, upon implementation and following revision of the Policy.
- Available for reference at all times on the shared Drive.
- May be assigned to employees for review via the Linear Learning Management System.

For officers:

- Training to communicate the existence of the Policy, a summary of its provisions, and obligations as eligible recipients
 - For new officers, upon their commencement.
 - For existing officers, upon implementation and following revision of the Policy.

For all parties (internal, and external such as family members or suppliers):

- Publicly available on the Linear website for reference.

To raise questions about this policy, please email qa-team@linear.org.au.

RECORDS

All activities under this policy should be documented, with records generated including (but not limited to) the following items:

- Initial report by the whistleblower
- Communication between the whistleblower and recipient, such as
 - Acknowledgement of receipt and outcome of preliminary assessment (3.1)
 - Consent to disclosure of the whistleblower's identity, if applicable (3.2)
 - Updates to the whistleblower on the status of the investigation (3.4)
- Formal record of investigation and related activities (3.3)
- Reports to the Board and other relevant parties (3.4)
- Communication between Linear and the authorities (regulators, police), if applicable
- Communication between Linear and legal practitioners, if applicable (2.1)

Where non-written communication is used (e.g. face-to-face or via telephone) a summary of the conversation must be documented including the content, date and time.

Each involved party is to maintain the records generated by or provided to them, until the outcome of the investigation is finalised. Following this, all records are to be collated by the designated investigation officer and stored securely for an appropriate period (for issues related to the conduct of a clinical trial, at least 15 years in accordance with the applicable regulatory requirements).

REVISION STATUS

Version	Description of Change	Implementation Date
00	Initial document (external to Linear Quality Management System)	31 Dec 2019
01	Initial document (as part of Linear QMS, with resultant formatting changes) Changes to involved parties, including removal of the Human Resources Manager as a designated recipient and investigation officer (replaced with Head of Quality Assurance); clarification of "senior manager" at Linear; and reiteration of protections for disclosure to legal practitioners. Addition of content on relevance to non-Linear entities, including HPIMR. Addition of content regarding generation and storage of documentation. Detail added regarding particular legal matters including references to the Therapeutic Goods Act 1989 and Taxation Administration Act 1953.	22 Apr 2020