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WALES

Pwyllgor Gwasanaethau Iechyd
Arbenigol Cymru (PGIAC)
Welsh Health Specialised
Services Committee (WHSSC)

PROTOCOL FOR DEALING WITH (1) CONCERNS, UNDER THE NATIONAL HEALTH SERVICE (CONCERNS, COMPLAINTS AND REDRESS ARRANGEMENTS) (WALES) REGULATIONS 2011, WHICH RELATE TO SPECIALISED SERVICES WITHIN WALES AND (2) CONCERNS REGARDING THE FUNCTION OF THE WHSS TEAM

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1.0 INTRODUCTION

- 1.1 Each Local Health Board (LHB) is accountable, through its statutory responsibilities, to use its resources to plan, fund, design, develop and secure the delivery of primary, community, in-hospital care services and specialised services for their population. For a number of national services, this can only be achieved by working collaboratively with all LHBs. Welsh Health Specialised Services Committee (WHSSC or the Joint Committee) is established on this basis of a shared, national approach to the joint planning of specialised and tertiary services on behalf of each LHB to which the Joint Committee is ultimately accountable. For a list of specialised services delegated to WHSSC please see the WHSSC website www.whssc.wales.nhs.uk
- 1.2 NHS organisations in Wales are committed to high standards in the management of concerns, which are fundamental to ensuring that service users and patients who notify either to the LHB or WHSSC are provided with a prompt, systematic and consistent response.
- 1.3 Concerns notified about care and treatment will be dealt with by the organisation providing the treatment. Concerns will be considered under The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011. Provider organisations must, as part of the contractual agreement, advise the LHB in which the patient is resident that a complaint has been made and the LHB will ensure that this is reviewed in conjunction with the WHSSC Quality and Patient Safety Joint Sub Committee.
- 1.4 Concerns notified about individual patient funding decisions will be handled by the LHB that covers the area in which the patient is resident, in accordance with the Individual Patient Funding Policy agreed by Welsh Government.
- 1.5 Concerns notified about the function of the WHSS Team (for these purposes including Joint Committee members and WHSS staff), if not resolved internally, will be dealt with by the Host LHB on behalf of all LHBs in Wales. A flowchart which outlines the WHSSC internal process to be used when dealing with concerns relating to the function of the WHSS Team can be found in Annex (i).
- 1.6 In recognition of the potential for confusion arising from the range of health organisations with which people might be in contact this protocol aims to provide an effective means of bringing together the

organisations in the interest of providing a responsive and effective service for concerns.

2.0 PURPOSE

2.1 In a complicated healthcare service environment, the more general benefits of a joint organisation protocol will be measured in terms of:

- Reduction of confusion for service users and patients about how concerns will be dealt with, and by whom;
- Clarify about the respective roles and responsibilities of organisations; and
- Enhancement of inter-organisation co-operation.

2.2 This protocol seeks to clarify responsibilities across the organisations and to set out a framework for inter-organisation collaboration in the handling of concerns to ensure:

- A single consistent and agreed contact point for individuals notifying of a concern;
- Regular and effective liaison and communication between concerns managers; and
- That learning points arising from concerns, covering more than one body, are identified and addressed by each organisation.

3.0 AIM

3.1 To provide a framework for dealing with concerns involving WHSSC and LHBs in Wales to ensure that concerns notified receive a seamless, effective service regardless of the organisations involved within the health economy.

4.0 DEFINITIONS

4.1 A "concern" ("*pryder*") means any complaint; notification of an incident concerning patient safety or, save in respect of concerns notified in respect of primary care providers or independent providers, a claim for compensation.

4.2 Signatory Organisations – means all organisations listed in Appendix A

4.3 "Responsible Body" is defined as an NHS body, a primary care provider or an independent provider.

5.0 ROLES AND RESPONSIBILITIES

5.1 Designated Independent Member

The designated Independent Member is responsible for the strategic overview of WHSSC arrangements for dealing with patient safety concerns, compliance with the arrangements and to ensure that there is learning from concerns.

The designated Independent Member within WHSSC is the Chair of the WHSSC Quality and Patient Safety Joint Sub Committee.

5.2 Responsible Officer Member

The designated senior lead officer is responsible for the effective day to day operation of the arrangements for dealing with patient safety concerns in an integrated manner.

The designated senior lead officer within WHSSC is the Director of Nursing & Quality Assurance.

5.3 Senior Investigations Manager

The senior investigations manager is responsible for the handling and consideration of patient safety concerns notified in accordance with the NHS (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 - Putting Things Right.

The Senior Investigation Manager within WHSSC is the Head of Quality & Patient Care.

5.4 Signatory Organisation's Patient Safety Concerns Managers

5.4.1 For each signatory organisation, the designated patient safety concerns manager is responsible for co-ordinating whatever actions are required or implied by this protocol.

5.4.2 The designated concerns manager is responsible for ensuring that there is appropriate communication and co-operation with other concerns managers. The concerns manager is responsible for ensuring that an agreement is reached with regards to who will take the lead role for individual concerns notified relating to specialised services.

5.4.3 The lead concerns manager is responsible for actions to be taken under the Regulations and this protocol when a concern is notified.

5.4.4 The designated concerns manager is responsible for ensuring arrangements are in place for cover should a

concern arise when he/she is on leave. The details of the suggested second contact are given in appendix B.

- 5.4.5 In the unlikely event that concerns managers are unable to reach agreement about any matter covered by this protocol, they should each refer the matter promptly to the relevant LHB directors/senior managers in their respective organisations for resolution.

5.5 Lead Organisation's Patient Safety Concerns Administration Teams

5.5.1 The Concerns Administration Teams are responsible for maintaining a record of the following matters:

5.5.1.1 Each patient safety concern notified to the Health Board

5.5.1.2 The outcome of each concern

5.5.1.3 Where the responsible body informed the person who notified the concern of:

(i) the likely period within which a response would be issued: or

(ii) any extension to that period, whether a response detailing the outcome of the investigation of the concern was sent to the person who notified the concern within that period, or any extended period.

5.5.2 The Concerns Administration Team of the lead organisation is responsible for ensuring that the following information is filed within the investigation folder:

- Any communication (verbal or written) with the individual who notified the concern
- Any communication relating to the concern notified
- Copies of expert opinions (if received/requested)
- Copy of the relevant medical records (this maybe an electronic copy e.g. CD)
- Statements received as part of the investigation
- The final investigation report

6.0 FACTORS TO DETERMINE THE LEAD ORGANISATION

6.1 The following factors should be taken into account when determining which organisation will take the lead role with any patient safety concerns relating to specialised services:

- 6.1.1 Concerns about care and treatment will be dealt with by the organisation providing the treatment;

- 6.1.2 If a disproportionate number of the issues in the concern relate to one organisation compared to the other organisation(s);
- 6.1.3 The organisation that originally receives the concern (should the seriousness and number of concerns prove broadly equivalent);
- 6.1.4 If the individual notifying the concern has a clear preference for which organisation takes the lead;
- 6.1.5 If it clear from the outset that there is proven qualifying liability in tort that may attract financial compensation then the investigation must be led by the LHB;
- 6.1.6 The organisations can agree separately from the above should other factors be pertinent. For example, if they impact on the individual organisation's governance arrangements.

7.0 PROCESS

- 7.1 A flowchart which outlines the WHSSC internal process to be used when dealing with patient safety concerns relating to specialised services can be found in Annex (ii).
- 7.2 It is desirable, where possible, for all responses to be provided to the individual notifying the concern as a composite, or at least to be delivered within a single cover. The Concerns Managers will need to co-operate closely for this purpose, in agreement with the individual.

8.0 PATIENT SAFETY CONCERNS ABOUT ONE ORGANISATION WHICH ARE NOTIFIED TO ANOTHER ORGANISATION

8.1 NHS Wales Arrangements

- 8.1.1 On occasions an individual may notify a LHB of a patient safety concern which in its entirety relates with WHSSC or visa versa. This may be due to lack of understanding of which body is responsible for which service or because the individual notifying the concern chooses to entrust the information to a professional person with whom s/he has a good relationship.
- 8.1.2 When a patient safety concern regarding a LHB is notified to WHSSC the Head of Quality & Patient Care of WHSSC should contact the individual notifying the concern within two working days. They should seek consent to share and

forward the concern to the LHB as they are responsible for responding to the concern.

- 8.1.3 When a patient safety concern regarding a specialised service, for which WHSSC is responsible, is notified to a LHB the Concerns Manager of the LHB should contact the individual notifying the concern within two working days. They should seek consent to share and forward the concern to WHSSC to enable a joint investigation to be undertaken.
- 8.1.4 When a concern (including a serious incident) involving a specialised service delegated to WHSSC is reported to the Improving Patient Safety Team at the Welsh Government, a copy of the report must be shared with WHSSC. This will enable WHSST to provide assurance to the responsible committee.
- 8.1.5 In the event of several organisations receiving the concern as an apparent original, contact will be made, on receipt of the individuals consent, with the other organisations. A decision will be made as to which will be the 'lead organisation'. The lead organisation will acknowledge within two working days on behalf of all organisations involved and will clarify the concern and explain the role of the other organisations.

8.2 Cross Border Arrangements

- 8.2.1 On occasions an individual may notify a healthcare provider outside of Wales of a patient safety concern which in its entirety relates to WHSSC or vice versa. This may be due to lack of understanding of which body is responsible for which service or because the individual notifying the concern chooses to entrust the information to a professional person with whom s/he has a good relationship.
- 8.2.2 When a concern regarding a healthcare provider outside of Wales is notified to WHSSC the Head of Quality & Patient Care of WHSSC should contact the individual notifying the concern within two working days. They should seek consent to share and forward the concern to the healthcare provider for investigation and provision of a response to the person raising the concern.
- 8.2.3 When a concern (including a serious incident) involving a specialised service, provided outside of NHS Wales which is

commissioned by WHSSC, is reported to a foundation trust, trust, clinical commissioning group, regulatory body, or NHSLA, a copy of the report must be shared with WHSSC. This will enable WHSST to provide assurance to the responsible committee.

- 8.2.4 The concern should be dealt with in accordance with the relevant concerns procedure which applies to that organisation. However this does not prevent the person notifying the concern seeking advocacy assistance from their local CHC.

9.0 CONSENT FROM THE INDIVIDUAL NOTIFYING THE CONCERN TO THE SHARING OF INFORMATION BETWEEN AGENCIES

- 9.1 Nothing in this protocol removes the obligation to ensure that information relating to individual service users and patients is protected in line with the requirements of the General Data Protection Regulation, Data Protection Act, Caldicott Principles and the confidentiality policies of each signatory organisation. It is for this reason that the consent of individual notifying the concern must always be sought before information relating to the concern is passed between organisations. Moreover, the individual notifying the concern is entitled to a full explanation as to why his/her consent is being sought.
- 9.2 Consent to the passing on or sharing of information under this protocol should be obtained, in writing.
- 9.3 If the individual notifying the concern withholds consent to the concern being passed to the other organisation, the Concerns Manager of the organisation receiving the concern will seek to engage with him/her to resolve any issues or concerns about remit and responsibility and offer any liaison which could contribute to the resolution of the matter of concern. The individual notifying the concern should be reminded of his/her entitlement to contact the other organisation direct.
- 9.4 The only circumstances where consent is not required to share a concern is where the concerns contains information which needs to be passed on in accordance with Safeguarding Children or Protection of Vulnerable Adults procedures or other service user safety issues. In such cases, the individual notifying the concern would be entitled to a full written explanation as to the

organisation's Duty of Care and its obligation to pass on the information.

- 9.5 A template is available from the WHSSC Head of Quality & Patient Care, which records the consent of individual notifying the concern for their case records to be disclosed for the purpose of concerns investigations.
- 9.6 Close co-operation between Concerns Managers will be crucial in ensuring that confidential case file information is shared appropriately, and that the necessary safeguards are put in place. Information exchanged under this protocol must be used solely for the purpose for which it was obtained.

10.0 CONCERNS GRADING

- 10.1 It will be the responsibility of the lead organisation to ensure that an assessment is undertaken in order to determine the seriousness/urgency of the concern. This assessment will require communication with personnel in all affected organisations. Contact is to be made by the relevant Concerns Manager.
- 10.2 The assessment will be undertaken within Wales using the concerns grading agreed by NHS Wales.
- 10.3 The individual professional remains accountable within his/her relevant organisation for the information pertaining to the initial assessment.
- 10.4 When direct contact is made with the individual notifying the concern then it is the responsibility of the individual undertaking the investigation to be satisfied with the information pertaining to the initial assessment and make any necessary arrangements in response to any factors identified.
- 10.5 Where a concern might be shared, the lead organisation will confirm to the individual notifying the concern a named person, address and telephone number and identify each part of the concern is being investigated. This letter will also confirm registration of the concern and will be copied to other organisations involved in the concern.

11.0 ARRANGEMENTS FOR FINANCIAL COMPENSATION UNDER NHS REDRESS

11.1 If it clear from the outset, or if it is established during the investigation, that there is proven qualifying liability in tort that may attract financial compensation the LHB of residence will make the required arrangements under NHS Redress.

12.0 LEARNING FROM CONCERNS

12.1 All concerns services are fully committed to facilitating organisational learning and development through resolution of the concerns raised. Resolving the individual concern is only part of the process.

12.2 Taking positive steps to identify communication, procedural, operational or strategic issues within and across each agency is a vital role in ensuring a relevant and positive concerns service.

12.3 All concerns services will use the process of at least quarterly and annual reporting to support effective communication between organisations and share learning. These will include any findings and recommendations that have an inter-organisational impact.

12.4 When an investigation report, action plan or closure form is shared with the Improving Patient Safety Team at the Welsh Government or the relevant organisation in England and where it relates to a concern involving a specialised service for which responsibility has been delegated to WHSSC, a copy of the shared document must be provided to WHSSC. This will enable WHSSC to provide assurance to the responsible committee.

12.5 Concerns activity will be reported separately by the Head of Quality & Patient Care to the WHSSC Quality and Patient Safety Joint Sub Committee quarterly.

13.0 IMPLEMENTATION

13.1 The principles outlined within this protocol are in place and therefore it is not envisaged that there will be any difficulty implementing this protocol.

14.0 REVIEW

- 14.1 The operation of the protocol will be reviewed at least every three years or when statutory changes dictate.

15.0 RESOURCES

- 15.1 NHS Redress and the principles of NHS Redress has to be embedded within WHSSC and become an integral part of all roles. However, it is equally important to understand that effective concerns management requires resources, people, time and funding.

Management of concerns must achieve sustained high performance against mandatory standards which will translate into improved quality of care.

16.0 TRAINING

- 16.1 Line Managers must ensure that new starters are aware of this protocol, induction arrangements and of their individual departmental processes.
- 16.2 It is the responsibility of individual Line Managers to inform the Head of Quality & Patient Care of the requirement where specific staff training needs are identified, particularly in relation to the implementation of new or updated documents.

17.0 EQUALITY

- 17.1 The Equality Impact Assessment (EQIA) process has been developed to help promote fair and equal treatment in the delivery of health services. It aims to enable WHSSC to identify and eliminate detrimental treatment caused by the adverse impact of health service policies upon groups and individuals for reasons of race, gender re-assignment, disability, sex, sexual orientation, age, religion and belief, marriage and civil partnership, pregnancy and maternity and language (Welsh).
- 17.2 This protocol has been subjected to an EQIA. The Assessment has shown that there will be no adverse effect or discrimination made on any individual or particular group.

18.0 REFERENCES / FURTHER INFORMATION

Welsh Government (2011) *2011 No. 704 (W.108) National Health Services Wales: The National Health Services (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011*; accessed 1st May 2012 from [here](#)

Welsh Government (2012) *Putting Things Right – Guidance on dealing with concerns about the NHS from 1 April 2011*; accessed 1st May 2012 from [here](#)

Welsh Government (2011) *Guidance on the Reporting and Handling of Serious Incidents and other Patient Related Concerns / No Surprises*; accessed 1st May 2012 from [here](#)

Appendix A

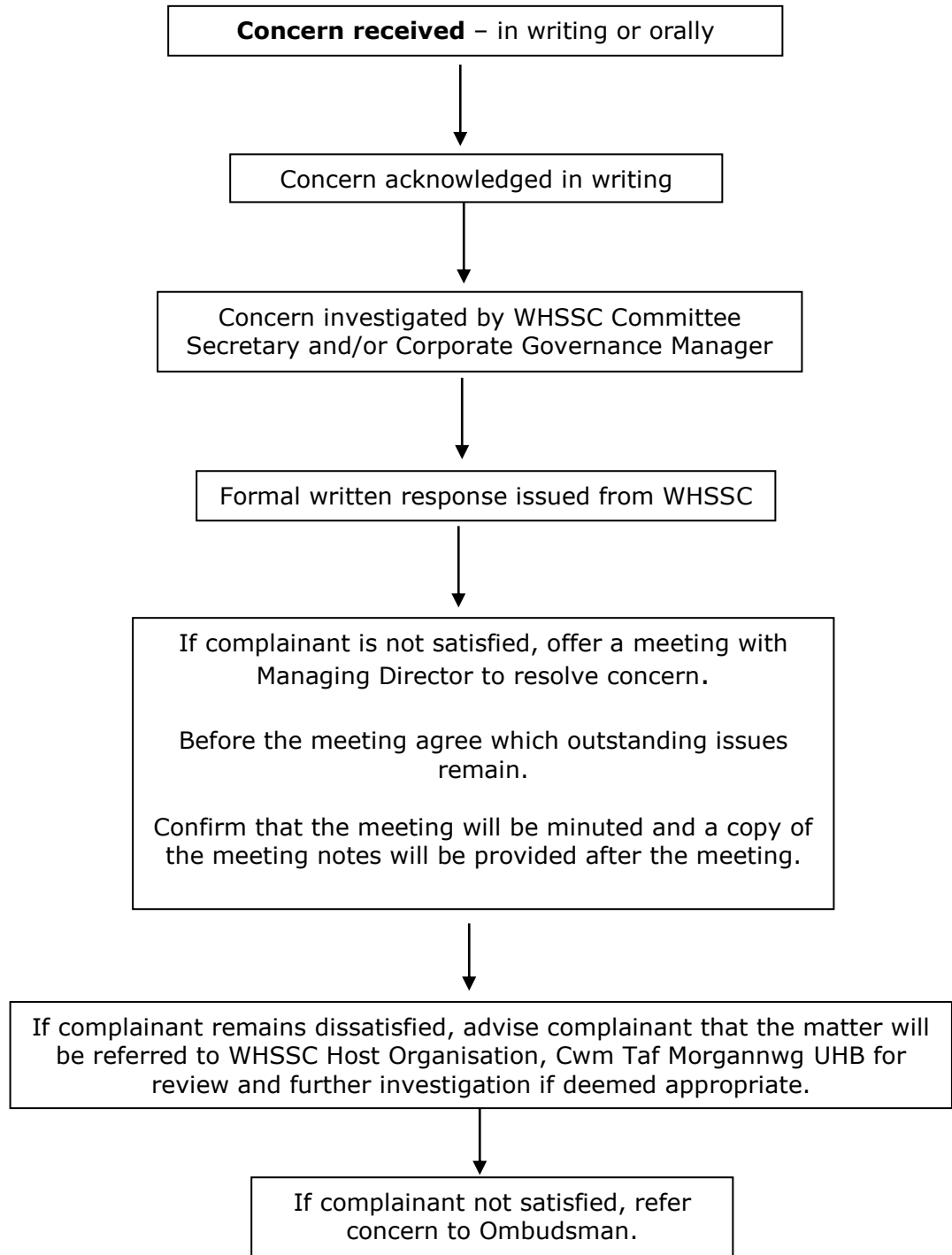
Signatory Organisations

Aneurin Bevan University Local Health Board
Betsi Cadwaladr University Local Health Board
Cardiff and Vale University Local Health Board
Cwm Taf Morgannwg University Local Health Board
Hywel Dda University Local Health Board
Powys Teaching Local Health Board
Swansea Bay University Local Health Board

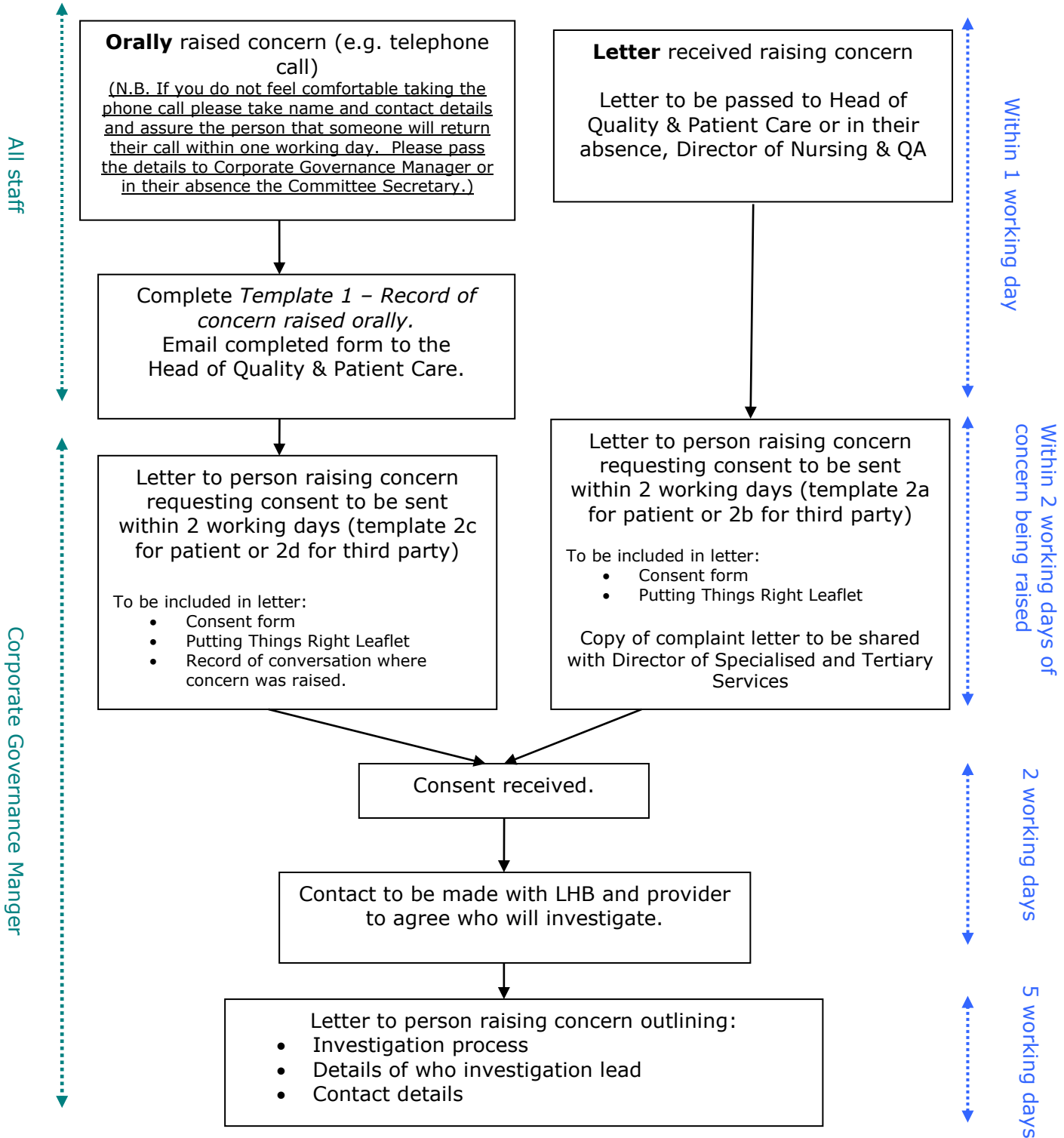
Appendix B

Organisation	Contact details
Aneurin Bevan UHB	Puttingthingsright.ABHB@wales.nhs.uk
Betsi Cadwaladr UHB	BCU.ConcernsTeam@wales.nhs.uk
Cardiff and Vale UHB	concerns@wales.nhs.uk
Cwm Taf Morgannwg UHB	CTHB_Concerns@wales.nhs.uk
Hywel Dda UHB	hdhb.patientsupportservices@wales.nhs.uk
Powys THB	concerns.qualityandsafety.POW@wales.nhs.uk
Swansea Bay UHB	SBU.LetsTalk@wales.nhs.uk
Welsh Health Specialised Services Committee	WHSSC.generalenquiries@wales.nhs.uk

Flowchart for concerns notified about the function of the WHSS Team.



WHSSC Flow Chart for the Management of Patient Safety Concerns



Templates are available on request from the Head of Quality & Patient Care.