RESEARCH COLLABORATION AGREEMENT

AUSTIN HEALTH
(ABN 96 237 388 063)

and

<Collaborating entity>
(ABN)
(Collaborator)

RESEARCH COLLABORATION AGREEMENT
THIS AGREEMENT shall come into effect on the Commencement Date and shall terminate on the Termination Date.

BETWEEN:

Austin Health of Studley Road, Heidelberg VICTORIA, 3084 Australia, a body incorporated pursuant to the Health Services Act 1988 (Austin Health),

AND

<Collaborating entity (ABN)> of <address> Australia (Collaborator);

Relevant Site(s):
1. [name of site] (Study Lead: [name, role, phone number, email])
2. etc

RECITALS:

A. Austin Health in collaboration with other co-investigators is conducting a study of the prevalence of advance care directives in Australia.

B. Austin Health will engage many collaborators across Australia to collect data from different sites.

C. Austin Health and the Collaborator have agreed to collaborate on a research project for the investigation of advance care directive prevalence at the Collaborator’s site(s) on the terms and conditions set out in this Agreement.

NOW IT IS AGREED:

1. DEFINITIONS AND INTERPRETATION

1.1 In this Agreement unless the contrary intention appears:

Activity means the project to be performed by the Collaborator under the terms of this Agreement and as described in this Agreement;

Agreement means this agreement including any schedules or annexures and any amendment thereto in writing;

Background Intellectual Property means inventions, technology, know-how and Confidential Information and all Intellectual Property Rights belonging to or under the control of a Party as at the Commencement Date which are required for the conduct of the Research Project, details of which are set out in Item 3 of Schedule 1;

Business Day means a day not being a Saturday, Sunday or declared public holiday in Melbourne, Victoria;

Commencement Date has the meaning given in Item 1 of Schedule 1;

Confidential Information in relation to a party, means all knowledge, information (including scientific, business, patient, staff and financial information), inventions, improvements, documents, drawings, samples, devices, demonstrations, trade secrets, know-how and other information of whatever description and all other commercially valuable information of that party and which that party regards as
RESEARCH COLLABORATION AGREEMENT

confidential to it (or which it designates as confidential) and all copies, notes and records as well as all related information generated by, or that comes into the possession (howsoever occurring) of, the other party based on or arising out of any such disclosure, but does not include information which:

(a) is in the public domain at the time of disclosure to the other party;

(b) is published or otherwise becomes part of the public domain but not in breach of any other obligations of confidence;

(c) at the date of disclosure to the other party was already properly in the possession of the other party without an obligation of non-disclosure to that party;

(d) is independently created by or on behalf of the other party by persons who had no knowledge of the disclosed information; or

(e) is required to be disclosed by law;

Data collector means a staff member(s) of the Collaborator or Austin Health who will collect the site data. They have been allocated to complete the research project, including conducting the file review, and have completed all study training provided by Austin Health;

Deliverables means the deliverables set out in Item 5 of Schedule 2;

Eligible Patients means those patients who are:

- aged 65 years or older; and
- admitted to the hospital or aged care facility for more than 48 hours, or visiting the general practice clinics on the day(s) of the research project

Ethics Application Reimbursement means reimbursement for a receipt provided to Austin Health for the Collaborator’s ethics application fee, if identified as necessary by the Collaborator in the application process for ethics approval of the Research Project, and previously paid by the Collaborator with prior written approval by Austin Health.

Head Funding Agreement means the agreement for the funding of Advance Care Planning Australia entered into by Austin Health and the Commonwealth Department of Health dated 6 September 2017;

Intellectual Property Rights means statutory and other proprietary rights in respect of trademarks, patents, circuit layouts, copyright, confidential information and all other rights with respect to intellectual property as defined in Article 2 of the Convention establishing the World Intellectual Property Organisation of July 1967;

Party means a party to this Agreement and its successors and permitted assigns;

Record/File means a comprehensive compilation of information traditionally placed in the medical record but also covering aspects of the person’s physical, mental and social health that do not necessarily relate directly to the condition under treatment. Also referred to as records, files, case notes, electronic health records, medical records, patient file, client file, care plan;

Record/File Review means the review of the health record/file completed by the data collector(s) using the data collection tool provided, for each of the identified eligible patients, looking for specific documentation of advance care planning and patient preferences for care, along with demographical and general clinical information, as outlined in the training provided to data collectors;

Relevant Sites means the site or sites listed after the Collaborator’s name at the beginning of the Agreement;
Representative in relation to a party means the Chief Executive Officer, Executive Director or site Manager of the party or such other person listed in Item 4 in Schedule 1 or otherwise nominated in writing by that party;

Research Project means the research project described in Item 3 of Schedule 1;

Research Results means all results of the Research Project including, without limitation, processes, formulae, reports, software, designs, and research data produced by Collaborator in the conduct of the Research Project and all Intellectual Property Rights therein;

Site Specific Assessment means a site-specific assessment of the research project submitted to Collaborator’s own Human Research Ethics Committee to confirm local capacity and capability to conduct the project. Reimbursement of the SSA fee will occur when a receipt is provided to Austin Health for the Collaborator’s site-specific application fee, if identified as necessary by the Collaborator in the application process for site ethics approval of the Research Project, and previously paid by the Collaborator with prior written approval by Austin Health.

Study means the national advance care directive prevalence study being conducted by Austin Health;

Study Lead means the key study coordinator contact for Austin Health to liaise with in respect of the research project. The Study Lead may also be a data collector. A change in Study Lead must be notified to Austin Health;

Tax means any tax, levy, charge, impost, fee, deduction, compulsory loan or withholding, which is assessed, levied, imposed or collected by any government agency; and

Termination Date has the meaning given to that term in Item 2 of Schedule 1.

1.2 In this Agreement, unless the contrary intention appears:

(a) the singular includes the plural and vice versa;

(b) a gender includes all genders;

(c) a reference to an individual, person, corporation, trust, partnership, unincorporated body or other entity includes any of them or any other legal person;

(d) reference to a party includes that party’s employees and authorised sub-contractors and agents;

(e) a reference to a clause or schedule is a reference to a clause of, or a schedule to, this Agreement;

(f) references to the words “include” or “including” are to be construed without limitation;

(g) a reference to legislation or to a provision of legislation includes a modification or re-enactment of it, a legislative provision substituted for it and a regulation or statutory instrument issued under it;

(h) reference to an “agreement” or “document” is to the agreement or document as amended, replaced or otherwise varied, except to the extent prohibited by this Agreement or by that other agreement or document;

(i) a reference to writing includes reference to printing, typing and other methods of producing words in a tangible and permanently visible form;

(j) if a word or expression is given a meaning, other parts of speech and grammatical forms of that word or expression have a corresponding meaning;
RESEARCH COLLABORATION AGREEMENT

(k) headings are for convenience only and do not affect interpretation;
(l) the recitals form part of this Agreement; and
(m) in the event of any conflict between the terms and conditions contained in the clauses of the Agreement and any part of the Schedules and annexures (if any) then the terms and conditions of the clauses will take precedence;

(n) this Agreement is not to be construed to the disadvantage of Austin Health because that party was responsible for its preparation.

1.3 The Collaborator:
(a) acknowledges that Austin Health is bound by the Head Funding Agreement, which imposes certain obligations on Austin Health regarding use of the Commonwealth funds provided under the Head Funding Agreement and the conduct of the Research Project. A copy of the standard grant agreement template may be found at:
(b) agrees to assist Austin Health to comply with the Head Funding Agreement, to act consistently and in accordance with the obligations imposed by the Commonwealth under the Head Funding Agreement, and to use its best endeavours not to do anything that causes Austin Health to breach its obligations under the Head Funding Agreement; and
(c) without limitation to clause 1.3(b), agrees to comply with the provisions set out in Schedule 4; and
(d) agrees that, to the extent of any inconsistency, the terms of the Head Funding Agreement will prevail over any other term of this Agreement.

2. TERM
Subject to clause 9, this Agreement will commence on the Commencement Date and expire upon the Termination Date.

3. CONDUCT OF THE RESEARCH PROJECT
3.1 The parties shall use all reasonable endeavours to carry out the Research Project to a high standard.
3.2 The Collaborator shall supply the Deliverables to Austin Health on or before, in respect of each Deliverable, the date specified for delivery in Item 5 of Schedule 2.
3.3 Austin Health and the Collaborator shall be responsible for obtaining all necessary ethical, administrative and governmental approvals required to conduct the Research Project as set out in Item 1 of Schedule 2.
3.4 Austin Health and the Collaborator shall supply all personnel, equipment, materials and other things necessary to perform the Research Project as expressed in Item 3 of Schedule 2.

4. REPORTING
The Collaborator shall submit to Austin Health reports on the conduct of the Research Project at the times and in the manner set out in Item 2 of Schedule 2.
5. **INTELLECTUAL PROPERTY**

5.1 Ownership of the Research Results shall vest in the manner set out in Item 2 of Schedule 3.

5.2 A Party’s Background Intellectual Property shall remain vested solely in that Party and nothing in this Agreement shall be deemed to give the other Party any rights to use or commercialise the same except as expressly provided by this Agreement, including Item 1 of Schedule 3.

5.3 Each Party hereby grants to the other Party a non-exclusive, royalty free licence to use, modify or adapt its Background Intellectual Property for the conduct of the Research Project.

5.4 Austin Health will acknowledge the Collaborator’s data and research contribution to the Study in the final report for the Study.

6. **CONFIDENTIALITY AND PUBLICATION**

6.1 Subject to the remaining provisions of this clause 6, each Party will treat all Confidential Information of the other Party as confidential and will not, without the consent of the other Party disclose or permit the same either to be disclosed to third parties or to be used, except solely as contemplated by this Agreement.

6.2 Each Party must use all reasonable endeavours to ensure that its Representatives comply with the obligations of confidentiality imposed upon it under this clause 6 as if those Representatives were bound in the same way.

6.3 Each Party must advise the other Party as soon as practicably possible of any breach of any confidentiality obligations under this Agreement of which it becomes aware.

6.4 A Party may disclose Confidential Information if required to do so by law or to its professional advisers, subject to the relevant adviser entering into an appropriate confidentiality undertaking.

6.5 Notwithstanding this clause 6, Austin Health may publish the Research Results.

6.6 Each Party’s obligations under this clause 6 shall survive termination or expiration of this Agreement.

7. **WARRANTIES**

7.1 Each Party warrants that it is the owner of its Background Intellectual Property free from all encumbrances and that to the best of its knowledge and belief at the time of entering into this Agreement, no third party has any rights or claim over the same.

7.2 Each Party warrants that it is not aware of any matter, fact or circumstance that is likely to adversely affect its ability to meet its obligations in relation to the Research Project, but if, during the term of this Agreement a conflict, or risk of conflict of interest, arises it shall notify the other Party immediately in writing of that conflict or risk.

7.3 Each Party will exercise all reasonable care and diligence in carrying out its obligations under this Agreement but to the fullest extent permitted at law each Party excludes all warranties, conditions or terms, implied in fact or at law, including any warranties that the Research Results are of merchantable quality or are fit for a particular purpose.

8. **INSURANCE AND INDEMNITIES**

8.1 Each Party shall effect and maintain adequate insurance to cover its conduct of the Research Project.
8.2 The Party with the right to use and commercialise the Research Results does so at its own risk.

8.3 Each Party releases and indemnifies and will continue to release and indemnify the other Party and its Representatives from and against all actions, claims, demands, costs and expenses (including the costs of defending or settling any action, claim or demand) made, sustained, brought or prosecuted in any manner directly based upon, occasioned by or attributable to any injury to any person (including death) or loss of or damage to property (including any infringement of Intellectual Property Rights) which may arise in relation to:

(a) or be a consequence of, disclosure or use of any Confidential Information in breach of this Agreement including but not limited to its use or commercialisation of the Research Results (if permitted);
(b) any unlawful or negligent act or omission of the Party or its Representatives under this Agreement;
(c) a breach of the terms and conditions of this Agreement by the Party; and
(d) the use of any product or process incorporating or produced using the Research Results.

8.4 The provisions of this clause 8 shall survive expiration or termination of this Agreement.

9. DEFAULT AND TERMINATION

9.1 Without prejudice to any other of Party’s rights, a Party (first Party) may by notice immediately terminate this Agreement if the other Party (Breaching Party):

(a) commits any serious or persistent breach of this Agreement;
(b) is guilty of any wilful misconduct or wilful neglect in the discharge of its duties under this Agreement;
(c) fails, within 14 days after receipt of written notice, to remedy any default in performance under this Agreement; or
(d) seeks relief under any bankruptcy or insolvency law or is the subject of liquidation or winding up proceedings, receivership, bankruptcy or similar, other than for the purpose of and followed by a reconstruction, amalgamation or re-organisation, or any person on the Research Project for whom the Breaching Party is responsible is convicted of any criminal offence.

9.2 Upon receipt of a notice of termination the Breaching Party must:

(a) stop work as specified in the notice;
(b) take all available steps to minimise loss resulting from that termination and to protect first Party Confidential Information;
(c) return to the first Party or destroy, as the case may be, any documents originating from the first Party which embody any first Party Confidential Information and must not keep any copies in any form.
(d) the Breaching Party shall upon request certify that any documents not returned to the first Party have been destroyed in accordance with clause 9.2(c).

9.3 Each Party acknowledges that damages may be an insufficient remedy for a breach by that Party of this Agreement in relation to protecting Confidential Information and that the other Party may be entitled to injunctive or other relief as the circumstances may require.
9.4 Notwithstanding other provisions of clause 9, a Party shall not be entitled to exercise its rights and remedies upon the default of the other Party if that default:

(a) is caused by an act or event that is beyond the reasonable control of that other Party;
(b) continues for less than one (1) month; and
(c) was not reasonably foreseeable at the time this Agreement was fully executed.

9A. STUDY-RELATED TERMINATION

If funding for the Study or for the Research Project is reduced or ceases or the Research Project is terminated for any other reason Austin Health may terminate this Agreement by giving the Collaborator seven days’ notice in writing.

10. NOTICES

10.1 Any notice, demand, approval, direction, offer, consent, agreement, specification, request, statement or other communication (Notice) required to be given or made under this Agreement must be

(a) in writing, in English;
(b) signed by a person duly authorised by the sender; and
(c) will be deemed duly given or made if delivered or sent in writing by prepaid post, facsimile transmission or email to the Party’s representative, as set out in Item 4 of Schedule 1:

10.2 Either Party may change its nominated representative, address, facsimile transmission number or email address for the purposes of this Agreement by giving notice of such change to the other Party within fourteen (14) days of the change.

10.3 Any notice or other communication will be deemed to have been received by the Party to which it was sent:

(a) in the case of hand delivery, upon the date of such delivery;
(b) in the case of prepaid post within Australia, on the third day next following the date of dispatch; or
(c) in the case of facsimile transmission, at the time of transmission, provided that following the transmission the sender receives a transmission report confirming complete error free transmission,
(d) in the case of email, at 10.00 am on the next day subject to the sender not receiving a delivery failure notification –

but if the result is that a Notice would be taken to be given or made on a day which is not a Business Day, or is later than 4.00 pm (local time), it will be taken to have been duly given or made at 10.00 am on the next Business Day.

11. GENERAL

11.1 Entire Agreement. This Agreement constitutes the entire agreement between the Parties and supersedes all prior communications, negotiations, arrangements and agreements, either oral or written, between the Parties with respect to the subject matter of this Agreement.

11.2 Variation. Any modification, alteration, change or variation of any term and condition of this Deed shall only be made in writing and executed by both Parties.
11.3 **Assignment.** Party may not assign the rights and obligations arising under this Agreement without the prior written consent of the other Party.

11.4 **Relationship.** The parties are independent contracting parties, and nothing in this Agreement makes any party the employee, partner, agent, legal representative, trust or join venture of the other for any purpose whatsoever, nor does it grant either Party any authority to assume or to create any obligation on behalf of or in the name of the other.

11.5 **Method of Disclosure.** The obligations in this Agreement apply irrespective of the method of disclosure whether in writing, in computer software, orally, by demonstration, description, inspection or otherwise.

11.6 **Costs and Taxes.** Each Party shall bear its own costs and Taxes arising out of the negotiation, preparation and execution of this Agreement.

11.7 **Waiver.** A waiver by a Party is only effective if it is in writing and a written waiver by a Party is only effective in relation to the particular obligation or breach in respect of which it is given. A Party's failure to exercise or delay in exercising a right or power does not operate as a waiver of that right or power and does not preclude the future exercise of that right or power.

11.8 **Further Assurances.** Each Party agrees to do all things and execute all deeds, instruments, transfers or other documents as may be necessary or desirable to give full effect to the provisions of this Agreement and the transactions contemplated by it.

11.9 **Severance.** If any provision of this Agreement is invalid or unenforceable, such provision(s) shall be deemed deleted but only to the extent necessary and the remaining provisions of this Agreement shall remain in full force and effect.

11.10 **Time of the essence.** Time is of the essence in the performance of any obligation or for anything that is required to be done pursuant to this Deed.

11.11 **Counterparts** This Agreement may be executed in counterparts and exchanged by email.

11.12 **Governing Law.** This Agreement is governed by the laws of the State of Victoria and each Party submits to the exclusive jurisdiction of the courts of that State.

12. **SURVIVAL**
Clauses 1, 5, 6, 7, 8, 11, and this clause 12 survive the expiration or termination of this Agreement.
## Schedule 1

<table>
<thead>
<tr>
<th>Item 1</th>
<th>Commencement Date</th>
<th>On execution</th>
</tr>
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<tbody>
<tr>
<td>Item 2</td>
<td>Termination Date</td>
<td>28 February 2019</td>
</tr>
<tr>
<td>Item 3</td>
<td>Research Project</td>
<td>Advance Care Directive Prevalence Study at the Relevant Sites.</td>
</tr>
</tbody>
</table>

**Responsibilities of Austin Health are to:**

- Oversee the project and provide training, support and advice as required
- Provide ethics approval as set out in Schedule 2 Item 1
- Provide training for the data collectors
  - Webinar training session(s) in data collection
  - A training manual to supplement the training program.
- Provide all data collection tools
- Provide access for data collectors to advice and support regarding any questions that may arise about the study and advance care planning during or after the research project, including
  - A package of electronic and hard copy information about the research project and advance care planning
  - A telephone advisory line
- Provide the Collaborator with an individualised, de-identified report of their site-specific results of the study
- Provide recognition of the Collaborator site participation in the research project and prevalence study

**Responsibilities of the Collaborator are to:**

- If agreed with Austin Health, gain site specific approval for ethics if any additional ethics approval is required within six weeks of notification of successful application
- Ensure the research project is conducted in compliance with all stipulations of the
study protocol, the conditions of the ethics committee approval with the NHMRC National Statement on ethical Conduct in Human Research (2007) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95)

- Be able to provide a data collector(s) and other necessary resources to ensure completion of the research project in the allocated timeframe; if general practice, allow access by Austin Health data collector staff
- Provide access for data collectors to computers and/or tablets with a reliable internet connection, and allow access to the secure web-based database to enable data recording
- Provide email and/or telephone access for the data collectors
- Provide time for the Study Lead and additional data collectors to complete online data collection training
- Have a patient/client information management system with the ability to extract and de-identify, for each Relevant Site, a minimum of 30 records/files on the day(s) of the research project
- Have data collector(s) who:
  - have access to the records/files
  - have experience in retrieving information from the records/files
  - can maintain patient privacy and confidentiality
- Enter completed data into the online database or paper tool provided within the specified time period as per the training provided
- Provide receipts to Austin Health for any ethics application fee paid
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Item 4  Representatives

Austin Health:
Dr Karen Detering
Medical Director
Advance Care Planning
Austin Health
145 Studley Rd
Heidelberg
Victoria Australia 3084

Phone: 03 9496 5660
Email: acpa@austin.org.au

Collaborator:
[name]
[role]
[phone]
[email]
[organisation name]
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Schedule 2

RESEARCH PROJECT, FUNDING AND REPORTING REQUIREMENTS

Item 1  Party responsible for obtaining all necessary ethical, administrative and governmental approvals

Austin Health is responsible for obtaining ethical approval to conduct the Study of which the Research Project forms part from a recognised Human Research Ethics Committee (Study Ethics Approval).

The Collaborator is responsible for obtaining and managing any additional agreed ethical approvals required to conduct the Research Project at the Relevant Sites, other than the Study Ethics Approval.

The Collaborator will be responsible for obtaining all necessary approvals required to conduct the Research Project at the Collaborator’s site.

Austin Health is responsible for obtaining all other necessary administrative and governmental approvals required to conduct the Study.

Item 2  Reports

No reports are required.

Item 3  Items supplied by the parties

Austin Health shall supply personnel, equipment, materials and other things necessary to oversee the Research Project.

The Collaborator shall supply all other personnel, equipment, materials and other things necessary to perform the Research Project.

Item 4  Payment

Austin Health will pay to the Collaborator:

(a) If applicable, Ethics Application Reimbursement;

(b) If applicable, Site Specific Assessment Reimbursement.

Mode of Payment

Following notification in writing from Austin Health regarding the total amount payable, a valid tax invoice will be provided by the Collaborator and paid by Austin Health 30 days from the end of the month following the invoice date, provided the relevant funds have been paid by the Commonwealth Department of Health to Austin Health.
Item 5

<table>
<thead>
<tr>
<th>Deliverable/Milestone</th>
<th>Due Date</th>
</tr>
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<tbody>
<tr>
<td>1. A minimum of 30 (maximum of 50) health records/files are reviewed, and data submitted to Austin Health</td>
<td>November 2018</td>
</tr>
</tbody>
</table>
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Schedule 3

INTELLECTUAL PROPERTY AND COMMERCIALISATION ARRANGEMENTS

Item 1  Background Intellectual Property

A Party’s Background Intellectual Property shall remain vested solely in that Party and nothing in this Agreement shall be deemed to give the other Party any rights to use or commercialise the same except when this is required for the conduct of the Research Project.

Item 2  Ownership of Research Results

As set out below

Ownership of Research Results:
Intellectual Property arising out of the Research Program and in the Research Results shall be vested in Austin Health.
Austin Health grants the Collaborator a perpetual, worldwide, royalty-free and non-exclusive licence to use, copy and sub-license the Research Results for the purposes of the Research Project and for internal quality improvement purposes.
1. Activity

1.1 The Collaborator must in relation to the Research Results acknowledge the support of the Commonwealth Department of Health in the manner approved by Austin Health and the Commonwealth Department of Health.

1.2 The Collaborator acknowledges that it may be considered a ‘Commonwealth service provider’ for the purposes of the Ombudsman Act 1976 (Cth) and subject to investigation by the Ombudsman under that Act. Neither Austin Health nor the Commonwealth Department of Health will be liable for the cost of any such investigation by the Ombudsman.

1.3 The Collaborator must abide by any instructions and directions given by the Commonwealth Department of Health in relation to the Activity and/or this Agreement.

1.4 The Collaborator must not assign or sub-contract any part of the provision of the Activity without the prior written approval of both Austin Health and the Commonwealth Department of Health. Such approval may be given subject to any conditions considered appropriate by either Austin Health or the Commonwealth Department of Health.

1.5 The Collaborator must not take any action or fail to take any action which would cause Austin Health to breach the Head Funding Agreement.

2 Funding

2.1 The only amounts payable by Austin Health to the Collaborator are the amounts specified in Item 4 of Schedule 2. All other costs, charges, fees and expenses for or arising out of or in connection with the provision of the Activity must be paid by the Collaborator.
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EXECUTED by the Parties on the last date hereinafter appearing:

SIGNED for and on behalf of Austin Health (ABN 96 237 388 063) by its duly authorised representative in the presence of:

..........................................................................................................................................................
Signature of authorised person

Witness (Signature)..................................................................................................................................
Name of authorised person (print)

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Name of Witness (print)..................................................................................................................................
Position

..........................................................................................................................................................
Date

SIGNED for and on behalf of <Collaborator (ABN)> by its duly authorised representative in the presence of:

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Signature of authorised person

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Signature of Witness

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Office held

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Name of authorised person (print)

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Name of Witness (print)

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Date