The Leg Club® Industry Partners

CODE OF PRACTICE

PATIENTS COMMUNITY

PRACTICE AND DISTRICT NURSES

LEG CLUB®

www.legclub.org

Leg Club Industry Partners

BRADFORD ON AVON
LEG CLUB
OPEN
EVERY WEEK
Starts 9am

The Leg Club® Industry Partners Code of Practice

This document has been developed by Ellie Lindsay OBE Life President of the Lindsay Leg Club® Foundation in conjunction with the Leg Club Industry Partners, September 2018.

The aim of this Code of Practice is to ensure the Industry Partners, and nurses working in the Leg Clubs have clear and identified parameters in their professional relationship. This will ensure those members requiring treatment receive safe, competent, evidence-based care.

The Code covers the promotion and supply of wound care and other products to nurses working in, and members of, the Leg Clubs. It has been drawn up in consultation with the Leg Club Industry Partners and takes into account the Nursing and Midwifery Council (NMC) Code of Professional Conduct: The Code: professional standards of practice and behaviour for nurses and midwives (2015) www.nmc-uk.org (Appendix 1), the Surgical Dressing Manufacturers Association (SDMA) Code of Practice (2018) (www.sdma.org.uk) (Appendix 2) and the Association of British Pharmaceutical Industry (ABPI) Code of Practice (2016) www.abpi.org.uk (Appendix 3).

The provisions of The Leg Club Industry Code of Practice are identified below:

- **Professional meetings**
- **Activities of representatives**
- **Supply of samples and promotional material**
- **Clinical evaluations, audits and case studies**
- **Provision of gifts and prizes**
- **The provision of hospitality**
- **Sponsorship for attendance at conferences**
- **And all other sales promotion.**

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Leg Club Industry Partners

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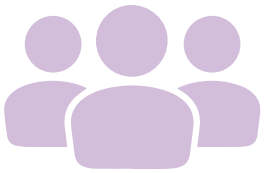
Complaints

Complaints relating to any aspect of this Code should be sent to the PA of the President (www.legclub.org) in the first instance. Complaints can be submitted by anyone. The company/nurse/Leg Club concerned will be approached by the Leg Club Clinical Consultant and must cease the activity of concern pending investigation. Following the Clinical Consultants report each complaint will be investigated and ruled upon by the Board of Trustees. If a breach of the Code has taken place the company/nurse/Leg Club will be required to take any other corrective action the Trustee Board sees fit. If necessary the complaint procedures of either the NMC, SDMA, ABPI or MedTech may be commenced.

Professional meetings

Professional meetings of nurses working in Leg Clubs may be attended by company representatives' dependent on the employing organisation's own policy or agreement for working with industry. Meetings must have a clear educational content that reflects the ethos of the Leg Clubs®.



Representatives

Representatives of LCIP companies can visit any Leg Club and support the nurses working in the Club. They must be sensitive to the needs of the Club and promote best practice for the members. (Appendix: 7)

As in the SDMA Code representatives must:

- At all times maintain a high standard of ethical conduct in the discharge of their duties and must comply with all relevant requirements of the Code.
- Not make claims or comparisons which are in any way inaccurate, misleading, disparaging, in poor taste or which discredit another company or the surgical dressings' industry.
- Ensure that the frequency, manner, timing and duration of their calls on customers do not cause inconvenience.
- Ensure that the wishes of individuals on whom representatives call and the arrangements in force at any particular establishment are strictly observed.

Samples

Samples may be provided to any nurses working in the Leg Club, subject to local employment conditions. Where promotional samples are provided for clinical use in order that potential users may familiarise themselves with the product. The samples provided must be a version of the product itself and meet the appropriate regulations, which would be the same as those applying to the marketed product. All samples must be for a named patient only, labelled as samples and be accompanied by the summary of product characteristics (SPC). The number of samples provided should fall within the limits laid out in the SDMA/ABPI or ABHI code of practice. (E.g. up to a maximum of ten (10) individual samples or one (1) standard pack).

Industry has a responsibility, where relevant, to provide education and training to explain the safe and effective use of their products.

Promotional material

Promotional material may be sent to Leg Clubs provided an identified need or interest in such information can reasonably be assumed. However; restraint must be taken in the frequency of such distribution. Mailing lists must be up to date and requests for removal from such lists must be undertaken promptly and should be in line with the GDPR regulations.

Clinical evaluations, audits or case studies

Clinical evaluations, audits or case studies related to products or services cannot be undertaken in Leg Clubs without the prior written consent of the Clinical Nurse Consultant of the Lindsay Leg Club Foundation. Submissions must be in writing on the attached submission form (Appendix 4) and include all relevant details. Decisions on such projects will be given within 28 days.

Such work must adhere to local ethical research and audit requirements, including local management and Ethics Committee approval if necessary (Appendix 5; Ethical decision-making flowchart). All staff involved must have a clear understanding as to the purpose of the study prior to its commencement. The Leg Club staff in cooperation with the relevant healthcare company should demonstrate clarity of data collection, analysis, results and recommendations, sharing these as appropriate with other Leg Club and colleagues. The product evaluation programme must be fit for the study, the documentation should be clear, easy to understand and quick to complete.

Gifts

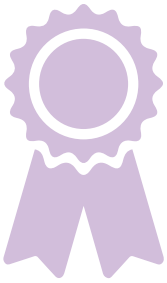
Gifts must not be given as an inducement to use or recommend a product. However, the provision of medical or educational goods and services that will enhance patient care or benefit the members of the Leg Club may be provided, with the prior written agreement of the Clinical Nurse Consultant of the Lindsay Leg Club Foundation or Board of Trustees. These may bear a corporate name but not a product name.

- Gifts should not include items intended for personal use. Gifts should be modest in value, i.e. up to a total value of £6.00 excluding VAT.
- Gifts of an educational nature donated to a Leg Club should not exceed a maximum value of £100 excluding VAT.
- No gifts or donations shall be offered or given as an inducement to prescribe, supply, administer or buy a dressing.

Schemes which enable customers, health care professionals and their employees obtain personal benefit are not acceptable.

Prizes

Prizes given directly to winners of any Industry competition should relate to product and/or the Leg Club. The value should be relative to the level of difficulty involved and in line with current SDMA guidance. They should be educational in nature and relevant to the use of the product.



Monetary prizes should be divided with 50% to the Leg Club and 50% to the nurses.

Hospitality

Hospitality must be secondary to the purpose of any meeting or educational event and not out of proportion. It must not include spouses or significant others unless they qualify as an attendee in their own right.

Conference sponsorship

Conference sponsorship, including travel and accommodation expenses, should be discussed with the prospective attendee's line manager prior to acceptance of any such offers. It must be shown to be relevant to the Leg Club and within local employment conditions. The level of funding will depend on the location and venue of the conference; some may be UK based others may be worldwide.

- Sponsorship may also include funding of venues, speaker's expenses, provision of audio visual equipment and/or refreshments for local conferences or workshops. The event should be relevant to, and reflect the ethos of, the Lindsay Leg Club Model. All such events should be organised with the full knowledge and participation of the Life President of the Lindsay Leg Club.
- Educational Grants may be offered to the Lindsay Leg Club conference organiser to identify clinicians to be supported. Individual companies must work within their Trade Association guidelines to support sponsorship of individual nurses.

A register of all gifts, prizes and sponsorship

A register of all gifts, prizes and sponsorship must be maintained using the attached proforma (Appendix 6) and submitted to the Leg Club administrator for inclusion in the central record on a 3-monthly basis. The list will be kept and maintained by the Leg Club secretary.

The provisions of the Code are to be observed in conjunction with the NMC, SDMA and ABPI guidance (Appendices 1,2 & 3) and may be subject to change at any time.

Appendix 1

Nursing and Midwifery Council (NMC) Code of Professional Conduct: The Code: professional standards of practice and behaviour for nurses and midwives (2015)

The purpose of the code is to:

- Inform the profession of the standard of conduct required of them in the exercise of their professional accountability and practice
- Inform the public, other professions and employers of the standard of professional conduct they can expect of a registered practitioner.

Clause 7 states:

7.1 You must behave in a way that upholds the reputation of the profession. Behaviour that compromises this reputation may call your registration into question even if it is not directly connected to your professional practice.

7.2 You must ensure that your registration status is not used in the promotion of commercial products or services, declare any financial or other interests in relevant organisations providing such goods and services and ensure that your professional judgement is not influenced by any commercial considerations.

7.3 When providing advice regarding any product or service relating to your professional role or area of practice, you must be aware of the risk that, on account of your professional title or qualification, you could be perceived by the patient or client as endorsing the product. You should fully explain the advantages and disadvantages of alternative products so that the patient or client can make an informed choice. Where you recommend a specific product, you must ensure your advice is based upon evidence and is not for your own commercial gain.

7.4 You must refuse any gift, favour or hospitality that might be interpreted, now or in the future, as an attempt to obtain preferential consideration.

Appendix 2

Surgical Dressing Manufacturers Association (SDMA) Code of Practice (2018)

The SDMA is dedicated to:

- Encouraging and expanding the use of safe and effective surgical dressings in health care markets
- Creating an agenda whereby innovation of technically advanced products and concepts can be encouraged
- Working in partnership with healthcare professionals to develop the appropriate use of products
- Influencing in a responsible way the creation of a beneficial regulatory environment
- Encouraging the adoption of high ethical standards of practice in the advertising and promotion of products.

Appendix 3

The Association of British Pharmaceutical Industry (ABPI) Code of Practice (2016).

Promotional material

There are extensive and detailed requirements relating to the content of promotional material – advertisements, mailings, details, etc. The overriding principle is that every piece of promotional material must be accurate and balanced, and should not mislead the reader in any way. Every statement must be 'capable of substantiation', which means there must be data to support it. Companies must have rigorous approval procedures to make sure that all material complies fully with the (ABPI) Code.

Representative calls

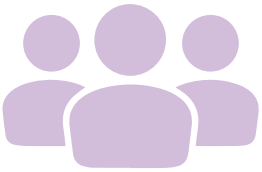
The principle here is that doctors and other health professionals should not be subjected to unacceptable selling techniques. The (ABPI) Code covers the timing and convenience of calls, and prohibits offering any sort of incentive to see a representative. The principle which applies to written material should be accurate, balanced, etc. and applies equally to everything that is said during a call.

Gifts to health professionals

Low value (up to £6.00) giveaways are allowed, provided they are relevant to medical practice – pens, pads, tourniquets, etc. Donations of items of greater value, e.g. medical equipment can be made by companies, but only if this is totally separate from promotional activity – which usually means separate from representative activity.

Sampling

Sampling of medicines is permitted, but only if this is done strictly in line with the detailed requirements of the (ABPI) Code. These cover the number of samples, sample requests and delivery and control of samples.



Meetings

The main requirement for company organised or sponsored meetings is that they must be primarily education activities, rather than social events. Hospitality can be provided but it must comply with the (ABPI) Code requirements in relation to cost, form and appropriateness to the occasion and to the attendees. Again, the principle is that there should be no suggestion that healthcare professionals are being 'wined and dined' by pharmaceutical companies and hence being unduly influenced in favour of their products.

Appendix 4

Seeking approval for clinical evaluations, audits, case studies or research in Leg Clubs®

Confidentiality

The Foundation's Clinical Governance Committee will review in full any submissions (e.g. academic research) from industry or elsewhere. Any discussions or work undertaken will remain confidential and will not be disclosed outside the Clinical Governance Committee, including the Foundation Board - except with the prior written agreement of the sponsor, or in an exceptional circumstance, and with approval from company/researcher concerned.

Process

Clinical evaluations, audits, case studies or research are welcomed by the Foundation in the pursuit of better patient care and to validate the efficacy of the Leg Club® model. However, these cannot be started without the prior agreement of the Clinical Governance Committee. Submissions must be made on the attached submission form (preferably electronically) and must include all relevant details.

Completed forms should be submitted to clinicalgovernance@legclub.org. Decisions on projects will normally be given within 28 days of receipt.

Research, audits and other projects must adhere to local ethical research and audit requirements, including local management and Ethics Committee approval where necessary (see: Appendix 1 Ethical decision making flowchart). If approval has not been received at time of submission, the Clinical Governance Committee must be reassured that the process is underway and be informed as to when approval is likely to be given.

Undertaking the Study

All Leg Club® staff and participating members must have a clear understanding of the purpose of the study prior before it starts. The primary investigator, in cooperation with Leg Club staff, should demonstrate clarity of data collection, analysis, results and recommendations.

The methodology must be fit for the purpose of the study. The documentation should be clear, easy to understand and quick to complete.

Insurance

Whilst most nursing activities within the Leg Club® will be covered by the employing Trusts vicarious liability, the use of new products, the attendance of researchers for data collection, etc. will not. The sponsoring company/researcher must have adequate insurance. This will be checked by the Clinical Governance Committee prior to approval being given for the study to start.

Publication

The Foundation is keen to raise the profile of the Lindsay Leg Club® model and share results from such studies with other Leg Clubs® as well as the wider health community. The Foundation is therefore eager that any studies or research undertaken are published. This may be in appropriate journals and presented at conferences. Any such publication must be compiled with the full knowledge and participation of the Foundation's Clinical Governance Committee.

Submission form for clinical studies or research

As identified in the Lindsay Leg Club® Foundation Partners Industry Code of Practice (2018), clinical evaluations, audits, case studies or research related to products or services cannot be undertaken in Leg Clubs® without the prior written consent of Ellie Lindsay and the Foundation's Clinical Governance Committee. Submissions must be in writing and include all relevant details.

The work must adhere to local ethical research and audit requirements, including local management and Ethics Committee approval, if necessary. All staff involved must have a clear understanding as to the purpose of the study before is starts. The primary investigator, in cooperation with Leg Club staff, should demonstrate clarity of data collection, analysis, results and recommendations, sharing these where necessary with other Leg Clubs® and colleagues. All documentation should be clear, easy-to-understand and quick-to-complete.

Appendix 4a

The Leg Club® Industry Partners submission form for clinical evaluations, audits or case studies

As identified in The Leg Club® Industry Partners Code of Practice (2018), clinical evaluations, audits or case studies related to products or services cannot be undertaken in Leg Clubs without the prior written consent of the Clinical Nurse Consultant of the Lindsay Leg Club. Submissions must be in writing and include all relevant details.

The work must adhere to local ethical research and audit requirements, including local management and Ethics Committee approval if necessary. All staff involved must have a clear understanding as to the purpose of the study prior to its commencement. The Leg Club staff in cooperation with any relevant healthcare company should demonstrate clarity of data collection, analysis, results and recommendations, sharing these as appropriate with other Leg Clubs and colleagues. All documentation should be clear, easy to understand and quick to complete.

PROJECT TITLE:

INVESTIGATOR

PRINCIPAL INVESTIGATOR: | JOB TITLE:

ADDRESS:

TELEPHONE NUMBER: | EMAIL ADDRESS:

PROJECT

WHAT ARE THE AIMS AND OBJECTIVES OF THE PROJECT?

PLEASE ATTACH A SUMMARY/PROTOCOL

WHAT DO YOU EXPECT THE PROJECT TO ACHIEVE?

WILL THIS STUDY BE: LOCAL ❑ REGIONAL ❑ NATIONAL ❑

METHODOLOGY: CLINICAL EVALUATION ❑ CLINICAL AUDIT ❑ CASE STUDY ❑

OTHER ❑ *PLEASE DESCRIBE:*

SPONSOR/FUNDING

NAME OF COMPANY SPONSORING OR FUNDING:

NAME OF PRIMARY FUNDING BODY:

PROPOSED START DATE: | PROPOSED END DATE:

STUDY SUBJECTS

WILL THE PROJECT INVOLVE RECRUITING: STAFF? YES ❑ NO ❑
PATIENTS? YES ❑ NO ❑

HOW MANY SUBJECTS WILL BE RECRUITED FOR THE PROJECT?

ETHICAL APPROVAL

IS ETHICAL APPROVAL REQUIRED? YES ❑ NO ❑

IF THE STUDY IS A MULTI-CENTRE STUDY DOES IT HAVE MREC APPROVAL? YES ❑ NO ❑

IF SO PLEASE GIVE MREC NUMBER:

HAS LREC APPROVAL BEEN GRANTED? YES ❑ NO ❑

IF SO PLEASE GIVE LREC NUMBER:

INDEMNITY

WHAT WILL BE THE INDEMNITY ARRANGEMENTS IF REQUIRED?

WHERE INDEMNITY IS NOT COVERED BY THE EMPLOYING TRUST PROOF OF INDEMNITY MUST BE PROVIDED.

FINANCE

SEPARATE INFORMATION IS ATTACHED REGARDING COSTINGS/FUNDING YES ❑ NO ❑

I confirm that:

- I am aware of my responsibilities under the Health and Safety Act both in respect of myself and other participants in the project
- I am aware of my responsibilities under the Data Protection Act
- All research will be carried out in accordance with the NHS Research Governance Framework (http://www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment/ResearchAndDevelopmentAZ/ResearchGovernance/fs/en)
- I will ensure the project does not commence until notification of approval from Clinical Nurse Consultant of the Lindsay Leg Club Foundation and the employing trust
- I confirm that the following are attached:
    - Project protocol
    - Any details of costing/funding
    - Copies of consent forms / patient information / audit tools
    - Proof of indemnity if required

Signed (Principal investigator): .....

Print Name: ..... Date: .....

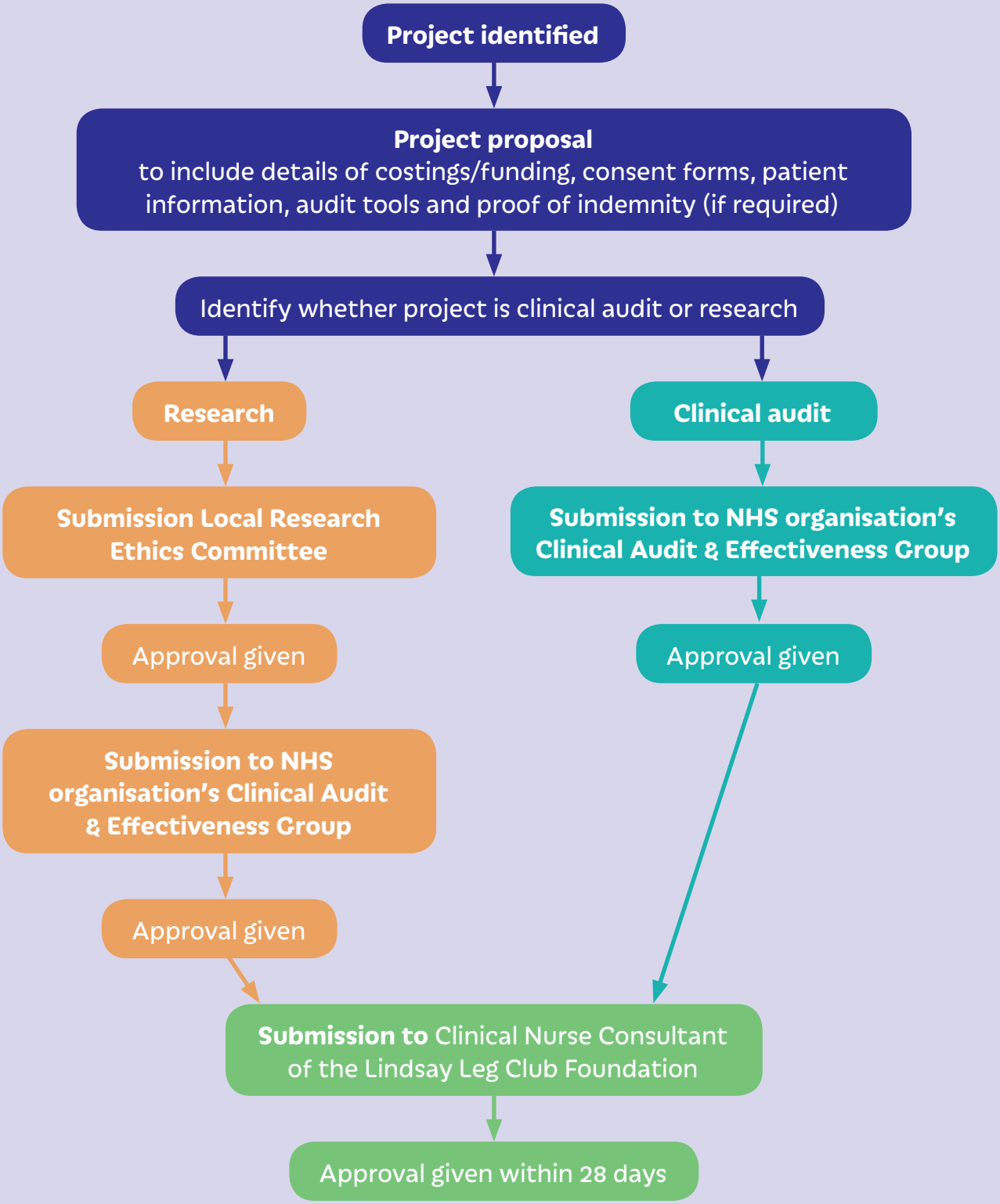
CCG/Trust/Organisation Manager's Agreement

Signed: .....

Print Name:..... Date: .....

Appendix 5

Ethical decision making flowchart



Appendix 6

The Leg Club® Industry Partners
Registers of gifts, prizes and sponsorship

DATE	COMPANY	GIFT (description, e.g. books)	SPONSORSHIP (type, e.g. venue, hospitality, conference fees, etc.	PRIZE (item, cash, etc.)	VALUE (£)

Appendix 7

Guidelines for LCIP Representative Attendance at a Leg Club

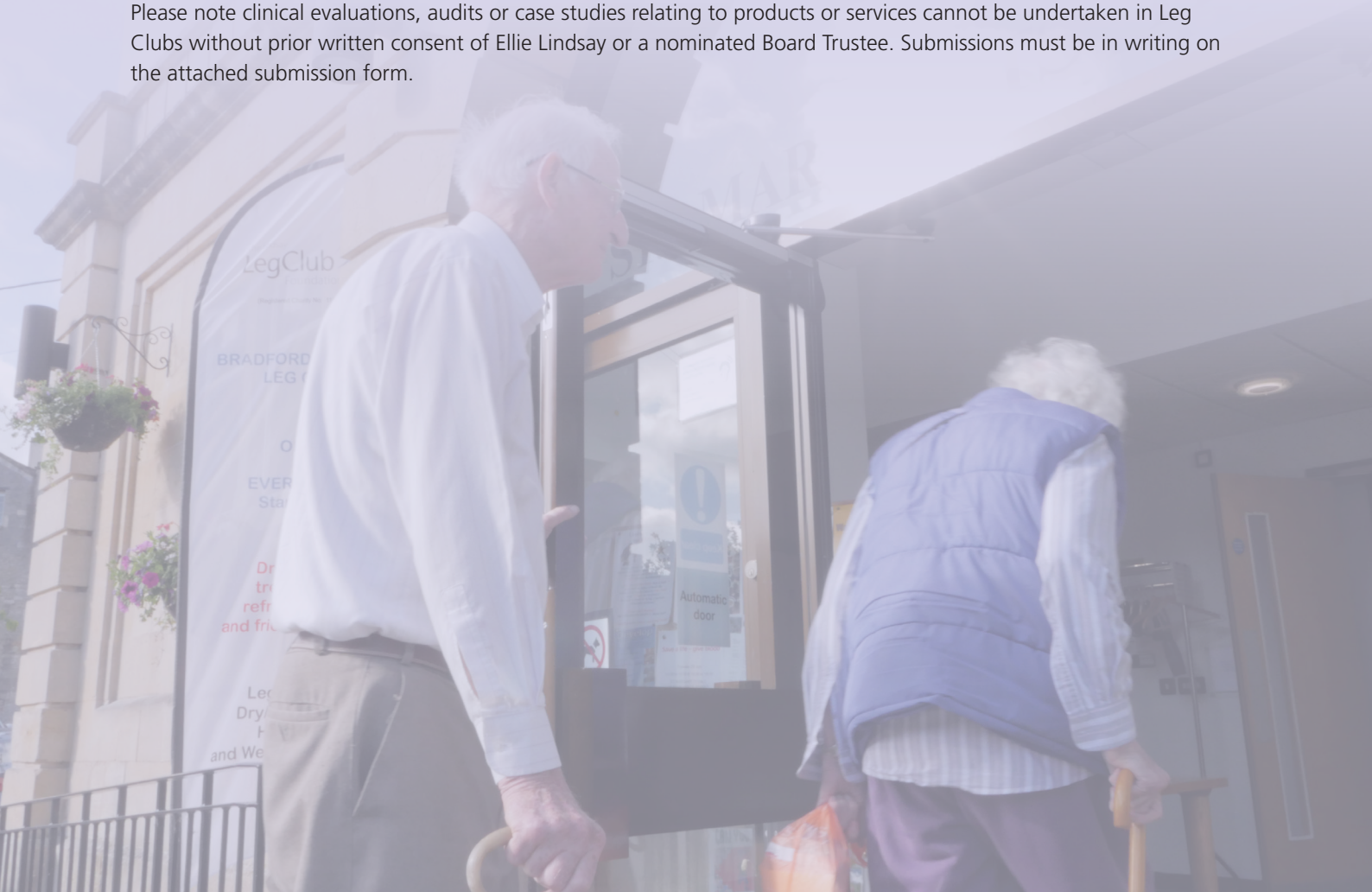
Representatives of companies can visit any Leg Club and support the Nurses working in the club. These visits should comply with the guidelines below. Leg Club Staff should not request regular timed visits or come to rely on the assistance of LCI Partners for any reason, clinical or administrative.

- Attendance must be agreed in advance by the Leg Club staff
- Representatives must introduce themselves on arrival and make it clear who they are representing.
- There is to be no clinical or physical contact between the representative and any Leg Club Member *(except to assist in the case of an emergency, or if an Honorary Contract is in place)*

As per the SDMA Code, whilst offering support at the Leg Club, the Company representative must ensure:

- At all times, a high standard of ethical conduct.
- That the frequency, manner, timing and duration of call do not cause inconvenience.
- NO product samples are used to treat Leg Club members
- If circulating marketing / promotional materials / samples to any Nurses working in the Leg Clubs, these are provided, subject to local employment conditions for familiarisation purpose only*.
- Not to make claims or comparisons which are in any way inaccurate, misleading, disparaging, in poor taste or which discredit another company.

Please note clinical evaluations, audits or case studies relating to products or services cannot be undertaken in Leg Clubs without prior written consent of Ellie Lindsay or a nominated Board Trustee. Submissions must be in writing on the attached submission form.



PATIENTS COMMUNITY

PRACTICE AND DISTRICT NURSES

LEG CLUB®

www.legclub.org

Leg Club Industry Partners

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