





Frequently Asked Questions

PakSurg1

- 1. What is PakSurg and what do we do?
- 2. What is the study about?

Eligibility and registration

- 3. Which hospitals can participate in this study?
- 4. What is an elective surgery?
- 5. Which surgical subspecialties are eligible for this study?
- 6. Which surgical procedures are included in this study?
- 7. What is a collaborator?
- 8. When can I register?
- 9. How can I register?
- 10. Can departments other than surgery participate in this study?
- 11. Is prior research experience required to join?

Why join PakSurg 1

- 12. <u>Will members from participating hospitals receive authorship or any other incentives?</u>
- 13. What is an authorship?
- 14. What is PubMed?

Data collection details

- 15. Do I need to come to AKU to participate in this study?
- 16. What is Redcap?
- 17. In what way can hospitals other than AKU contribute to the study?
- 18. Is there a requirement of mandatory minimum number of patients enrolled?
- 19. For hospitals other than AKU, what is the process of applying for participation in the study?
- 20. What is an ORCID ID?

Collaborator roles and details

- 21. How many members can be a part of one team?
- 22. How many teams can participate from each hospital?
- 23. Who can be an institutional lead collaborator?
- 24. What are the responsibilities of an institutional lead collaborator?
- 25. Who can be an institutional supervising consultant?
- 26. What are the responsibilities of an institutional supervising consultant?
- 27. Can I register myself if my centre does not have an institutional lead collaborator as of yet?

Local approval(s)

- 28. What is an institutional review board (IRB) or ethical review committee (ERC) approval?
- 29. What should I do if my institution does not have IRB or ERC?
- 30. What is a data transfer agreement (DTA)?
- 31. Are all institutes required to get a DTA signed?
- 32. What are the steps for processing a DTA before submitting it to the ERC/IRB?

For contact

33. If I have further queries, who can I reach out to?

1. What is PakSurg and what do we do?

PakSurg is the first national trainee-led surgical research collaborative in Pakistan. It is established by the Surgery Interest Group at the Aga Khan University to promote national coordination in surgical research.

Supported by the Department of Surgery and Centre for Global Surgical Care at the Aga Khan University, this collaborative network aims to initiate multicenter research studies across Pakistan to enhance surgical research output which will lead to an improvement in surgical outcomes in Pakistan.

2. What is this study about?

Our first study, PakSurg 1, aims to determine the epidemiology and risk factors associated with development of surgical site infections (SSIs) in Pakistan.

3. Which hospitals can participate in this study?

All hospitals in Pakistan where elective surgeries are performed.

4. What is elective surgery?

Elective surgery or elective procedure is surgery that is scheduled in advance and does not involve a medical emergency.

5. Which surgical subspecialties are eligible for this study?

A total of 9 subspecialities can participate: breast surgery, cardiac surgery, colorectal surgery, cranial surgery, general surgery, obstetrics & gynaecology, orthopaedics surgery, spine surgery, and vascular surgery.

6. Which surgical procedures are included in this study?

Collaborators can collect data from included procedures (<u>appendix – included</u> <u>procedures</u>) across 9 subspecialities.

7. Who is a collaborator?

A collaborator is any medical student, intern, resident, registrar, fellow, consultant, or faculty member who registers with PakSurg to participate in our study. All collaborators will be responsible for data collection at their centre.

8. When can I register?

The patient recruitment period will be from 1st September 2022 to 31st March 2023. All interested collaborators can join at any time till 1st March 2023 using the <u>interest form</u> at our <u>website</u>.

After registering your interest, a member of the outreach team will reach out to you and instruct you about further steps.

9. How can I register?

You can register by clicking here or from our website.

10. Can departments other than surgery participate in this study?

No. Only the prespecified subspecialities performing procedures listed in the <u>appendix</u> <u>– included procedures</u> can participate.

11. Is prior research experience required to join?

No prior research experience is required. Any medical student or doctor can join and collect data. Upon successful completion, all collaborators will receive PubMed citable authorship for their contributions.

12. Will members from participating hospitals receive authorship or any other incentive?

All successful collaborators who will complete data collection will receive PubMed citable authorship for their contribution in the resulting publication(s). Apart from authorship, the collaborators will also benefit from clinical exposure, networking, and research exposure.

13. What is an authorship?

An authorship is a recognition and evidence which an individual gets for participating and contributing to a research study. The authorship is a public record and any person can view your contribution in the study. It can also be mentioned as your personal achievement and academic excellence, in your CV or resume.

14. What is PubMed?

PubMed is a free resource supporting the search and retrieval of biomedical and life sciences literature. The PubMed database contains more than 34 million citations and abstracts of biomedical literature.

Highly reputed journals are indexed into PubMed.

15. Do I need to come to AKU to participate in this study?

No, participants are not required to travel to AKU to participate in this study.

Data collection will be done in your own hospital. The collected data will be uploaded on a secure Redcap server, which will be provided by the PakSurg steering committee.

16. What is Redcap?

Redcap is a secure web platform for building and managing online databases and surveys. Its access will be shared by PakSurg steering committee to collaborators.

17. In what way can hospitals other than AKU contribute to the study?

Hospitals all over Pakistan can join PakSurg 1 by registering their interest through our website. After contacting our team and getting appropriate local approvals (institutional review board or ethical review committee approval, as applicable) hospitals will collect data on eligible patients and submit it via Redcap.

18. Is there a requirement of mandatory minimum number of patients enrolment?

All consecutive patients undergoing included procedures (<u>appendix – included procedure</u>) over a one month period should be enrolled into the study. All included patients will be followed up till 30 days postoperatively.

19. For hospitals other than AKU, what is the process of applying for participation in the study?

All interested individuals will <u>register</u> their interest to our committee through the <u>website</u>. All registered individuals will then be contacted by a member of our outreach team with further instructions to register your institute (Figure 1).



Figure 1: Study process

20. What is an ORCID ID?

An ORCID ID is a unique, persistent identifier which can be made free of charge at ORCID.

This ID allow researchers to be uniquely identified for their research, scholarship, and innovation.

21. How many members can be a part of one team?

For each subspeciality, a mini-team of up to 3 collaborators can be made for one month period of data collection during the patient recruitment window of 1st September 2022 to 31st March 2023.

22. How many teams can participate from each hospital?

It is recommended for centers to participate in all subspecialities over all months. A maximum of 7 teams per subspecialty, over patient recruitment period of 7 months, can be made across all 9 subspecialties.

23. Who can be an institutional lead collaborator?

Any medical student, intern, resident, or fellow from an eligible centre can apply to be institutional lead collaborator.

24. What are the responsibilities of an institutional lead collaborator?

An institutional lead collaborator will be responsible for:

- → Coordinating teams in their centres by ensuring that no overlapping teams are collecting data from the same patients within the same time period.
- → Obtaining the necessary ethical approvals in their centres.
- → Inviting their colleagues to participate in the study and formulating additional data collection teams in their centre.
- → Providing information about their centre surgical capacity and facilities.
- → Same responsibilities as collaborators.

For these efforts, institutional lead collaborator will be awarded lead collaborator under the corporate authorship model.

25. Who can be an institutional supervising consultant?

An acting consultant, faculty members, or registrar from each of the specified surgical subspecialties from eligible centres can apply to be institutional supervising consultant.

26. What are the responsibilities of an institutional supervising consultant?

An institutional supervising consultant will be responsible for:

- → Leading and supervising institutional mini team(s).
- → Obtaining the necessary ethical approvals in their centres.
- → Inviting their colleagues to participate in the study and formulating additional data collection teams in their centre.
- → Providing information about their centre's surgical capacity and facilities.
 - Please note:
 - Only faculty members/consultants/registrars are eligible to become institutional supervising consultants.
 - If an institution registers for multiple subspecialties, there should be 1 supervising consultant per subspecialty registered.

27. Can I register myself if my centre does not have an institutional lead collaborator as of yet?

Yes. For a centre without an institutional lead collaborator, you can <u>register</u> on our website. A member of the outreach team will contact you and will guide you on receiving appropriate local approval(s) like institutional review board or ethical review committee approval.

28. What is an institutional review board (IRB) or ethical review committee (ERC) approval?

For any study that involves interaction and working with humans or animals, it is mandatory to receive IRB or ERC (whichever is applicable in your institution) approval prior to data collection. Collaborators need to consult their supervising consultant to obtain appropriate approval(s).

29. What should I do if my institution does not have IRB or ERC?

In such cases, you must receive a written permission from the next best available source. These can include hospital chief, chair of department of surgery, a supervising consultant, or an attending physician (see <u>template letter</u>).

30. What is a data transfer agreement (DTA)?

A Data Transfer Agreement (DTA) is a legal contract governing the transfer of non-human subject data or completely de-identified human subject data. It sets out the related protections, rights, and obligations of both parties and delineates the specific purpose(s) for which the data may be used.

31. Are all institutes required to get a DTA signed?

Yes. Institutes have to get a DTA signed from their IRB or ERC for study approval and site registration.

32. What are the steps for processing a DTA before submitting it to the ERC/IRB?

A template of the Data Transfer Agreement is available on our website. The agreement will require signatures from the concerned local authority from your institute. After the agreement is signed, it should be shared with our team via email. Once the signed DTA is approved by our team, the steering committee will add their signatures and you will be allowed to share the DTA with your institutional review committee.

33. If I have further queries, who can I reach out to?

For any further query, you can contact us at paksurg.aku@gmail.com. You can also stay updated about PakSurg and our future studies through our social media platforms:

Instagram: https://www.instagram.com/paksurg/

Twitter: https://twitter.com/paksurg

Facebook: https://www.facebook.com/paksurg/