# Ethical Considerations and Appropriate Oversight for projects involving mixed methods

NNSW LHD Proposal for projects involving mixed methods v5

Research is encouraged within Northern NSW Local Health District (NNSW LHD) as a means of informing the safe, effective and efficient delivery of health services. Quality Activities including Quality Improvement, Quality Assurance and Service/Program Evaluation can also be used to monitor or improve the quality of health services. Attempts to differentiate Quality Activities as separate to research by way of definition are generally unhelpful because they often utilise similar methods and pose similar risks and benefits to participants. Definitions for each activity are available [online](https://nnswlhd.health.nsw.gov.au/our-organisation/research/research-governance#quality-activities).

The Northern NSW LHD Research Office has established a [review pathway for Quality Activities involving a non-Human Research Ethics Committee](https://nnswlhd.health.nsw.gov.au/our-organisation/research/research-governance#quality-activities) (HREC) level of review. This document provides guidance on ethical considerations and appropriate oversight for Quality Activities proposing to undertake a project involving mixed methods (combines qualitative and quantitative research approaches) and details the process of submitting an application to the Research Office. **This review pathway can only be used by lead project officers who are** **employees of Northern NSW LHD *and* for projects that pose no more than low risk to participants (i.e. no more than discomfort)**. NNSW LHD supports a range of alternative ethical review pathways for projects which do not meet these criteria. Further information about NNSW LHD Research Ethics and Governance processes and review pathways is available [online](https://nnswlhd.health.nsw.gov.au/our-organisation/research/research-governance#quality-activities). Also described on this page is the standard process for other types of Quality Activities (e.g. **projects proposing to analyse existing data collected during standard/routine care in the form of retrospective data analyses**, and **projects involving primary data collection such as surveys, focus groups and interviews**) and **case study/series**. If required, please contact the NNSW LHD Research Office for further guidance by email: NNSWLHD-Ethics@health.nsw.gov.au or telephone: (02) 6672 0269.

To submit a Quality Activity application for review by the Research Office, please complete the following:

1. Quality Activity Proposal using the template provided.
2. Ethical Considerations checklist, [Appendix A](#EthicalConsiderationsChecklist),
3. Prepare/Collate any additional study material as required (e.g. survey tool, [Participant Information Sheet, Consent Form](https://nnswlhd.health.nsw.gov.au/sites/default/files/2022-11/nonHREC%20PICF%20template%20v1_20221107.docx)),
4. Obtain the signature and endorsement for the conduct of the project from your relevant Head of Department, and
5. Submit the form (in word format) *with* HoD endorsement and signature (electronic signature or scanned PDF document accepted) and supporting material by email to: NNSWLHD-Ethics@health.nsw.gov.au

If you are planning on **engaging the services of a Health Information Manager** (HIM) to obtain retrospective data, please provide evidence that the HIM is aware of the project and is willing to support it conditional on ethical and scientific review approval (e.g. providing a copy of the email correspondence with a HIM is sufficient as evidence). **To submit an amendment to an approved QA project**, please follow the instructions on the [Research Governance website](https://nnswlhd.health.nsw.gov.au/our-organisation/research/research-governance#quality-activities).

# Quality Activity Proposal for projects involving mixed methods (combining qualitative and quantitative research approaches)

### The Quality Activity template is designed to help you define the scope of your project and develop a plan for how you will undertake your project. This process helps to ensure that any subsequent findings align with the aims, the methods used meet an acceptable standard of scientific quality and any ethical and safety considerations are identified and addressed. The protocol template is designed for mixed methods projects and where *possible provides details of the type information* *required (in italics)* as well as sample responses.

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| **Project title:**  | *Use a descriptive, informative title that succinctly describes the study including the main project idea, study site, and that the study is mixed methods. For example, Evaluating patients’ pain 7 and 14 days after joint replacement surgery: a mixed methods study.*  |
| **Short title (if any):** | *Sometimes referred to as a running title* |
| **Site(s):** | *Please list all site(s) the project will be undertaken* |
| **Version Control:**  | Version 1, dated xxxx |
| **Purpose:** | *What is the main purpose for undertaking the activity? Please select all that apply.*

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| [ ]  Clinical Leadership Program | [ ]  Fellowship Training Program |
| [ ]  Coursework excluding higher degree research programs | [ ]  Program evaluation  |
| [ ]  Clinical practice improvement project e.g. clinical audit, quality improvement project |
| [ ]  Other, provide a description in your own words: |

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| **Project Team:** | **Lead Project Officer**: The lead project officer must be an employee of Northern NSW LHD for the duration of the project.

|  |  |
| --- | --- |
| Name: |  |
| Position: |  |
| Department: |  |
| LHD Employee Number:  |  |
| Telephone: |  |
| Email: |  |

**Project Officer**

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| --- | --- |
| Name: |  |
| Position: |  |
| Department: |  |
| LHD Employee Number:  |  |
| Telephone: |  |
| Email: |  |

*Copy and paste the table to add additional project officers.* |
| **Head of Department Endorsement:** | * I confirm that I am the relevant Head of Department for the above-named Project Lead including the service/data relevant to this project OR I have sighted evidence of approval from the relevant Department.
* I confirm that the lead project officer is, and will remain, an employee or agent of NNSW LHD for the duration of the project.
* I confirm I have read the QA Proposal and Ethical Considerations Checklist, and I agree with the assertions made by the Project Lead.

**Head of Department**

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| --- | --- |
| Name: |  |
| Position: |  |
| Department: |  |
| LHD Employee Number:  |  |
| Telephone: |  |
| Email: |  |
| SIGNATURE: |  |
| DATE: |  |

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| **Student involvement** | [ ]  Yes, I would be interested in having a medical or other student involved in this project (Please note that this cannot be guaranteed but you may be contacted at a later date when projects are required)[ ]  No, I am not interested in having a medical or other student involved in this project |
| **Background & Rationale:** | *Provide an introduction to the project, this may include a description of the problem and brief literature review of the area, and rationale/justification for the project (why is it important that you undertake this project, what is the evidence-practice gap you are trying to address).* |
| **Aims & Objectives:**  | *State the aim of the project (an aim describes the overall goal/intention of the project) and objectives of the activity/project (the objectives are the specific steps you will take to achieve your aim). These can be outlined as dot points.* |
| **Outcomes & Relevance:** | *Provide information on the potential benefits of the project (e.g. to inform future research, policy, planning and/or practice) and how the findings will be used to improve or inform service improvement.* |
| *Dissemination plan* | Where do you plan to disseminate the findings of the project*: (check all that apply and provide details as appropriate)*[ ] Internal report (please provide details): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ] External report (please provide details): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  Presentation (please provide details e.g. unit/department/organisation level, scientific conference): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  Publish in a peer-reviewed journal (please provide details): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  Other (please provide details): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |
| **Methods:** | **Study Methodology** (Check all that apply)

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| Qualitative methods: | [ ]  Focus group(s) |
|  | [ ]  Interviews |
| Quantitative methods: | [ ]  Retrospective data analyses of routinely collected data (Identifying and analysing routinely collected data) |
|  | [ ]  Cohort study (Identify participants/patients and follow them overtime) |
|  | [ ]  Case-control study (Selecting cases and controls) |
|  | [ ]  Cross-sectional study (Identify participants/patients and describe their characteristics at one point in time) |

**Mixed methods research designs:** (Select the one that best describes your project)[ ]  Convergent design (collecting and analysing qualitative and quantitative data separately and then comparing the two sets of results)[ ]  Explanatory sequential design (collecting and analysing quantitative data first, and the conducting the qualitative research to explain the quantitative results)[ ]  Exploratory sequential design (uses a qualitative approach to exploring the problem first, these qualitative results are then used to develop a new intervention, measure or instrument which is then used in the quantitative phase of the study)[ ]  Intervention design (quantitative outcomes are captured to determine the effect of an intervention, and qualitative data are collected to support the development of an intervention, understand the contextual factors during the intervention or explain the results)[ ]  Multistage evaluation design (multiple stages of data collection that may include various combinations of exploratory sequential, explanatory sequential, and convergent approaches)**Setting***Describe the setting of interest (e.g. ED/inpatient/outpatient/community), locations (e.g. hospital site(s)) and relevant dates (e.g. July – September 202X) e.g. period of recruitments, follow up and data collection (e.g. July – September 202X).***Participants (including eligibility criteria)***Give the eligibility criteria (inclusion/exclusion criteria), the sources used to identify participants (e.g. specific electronic medical records e.g. FirstNet, SurgiNet; referral) and the methods of screening and recruiting participants (i.e. face to face, telephone*). *Describe qualitative and quantitative criteria separately if different approaches are used.* **Variables** *Qualitative data collection:* *Describe your data collection methods and tools (e.g. use of interview / focus group questions, prompts, guides), use of audio/visual recording and/or field notes, duration of interviews / focus groups.**Quantitative data collection:**Using the table below, clearly list and define the variables you plan to collect including any exposures, predictors, potential confounders, and effect modifiers. This may include demographic information (e.g. age, sex, socioeconomic status), clinical information (e.g. diagnosis, disease or condition, specific treatment or procedure provided; give diagnostic/treatment codes if applicable) and potential confounders (e.g. comorbidities, other treatments received). For each variable, give the source of data and how it will be assessed/measured (as applicable).*

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| **Variable** | **Definition** | **Source of data**  | **Measured** |
| *e.g. Age* | *e.g. Age at recruitment* | *e.g. medical record* | *e.g. Years and months* |
| *e.g. Quality of life* | *e.g. Quality of life* | *e.g. Participant self-report* | *e.g. SF-6D* |
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*Add additional rows as required***Main study outcome variable(s)***Qualitative main outcome: e.g. ‘Understanding patient pain experience after a joint replacement*’*Quantitative main outcome:**Provide information on the main outcome variable(s), how it is defined (e.g. diagnostic/treatment codes, descriptive definition), the source of data and how it will be assessed/measured.*

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| **Main study outcome variable** | **Definition** | **Source of data**  | **Measure** |
| *e.g. Pain score* | *e.g. Pain score at 7 and 14 days* | *e.g. Participant self-report* | *e.g. 0-10 Visual analogue scale* |
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*Add additional rows as required***Study procedure***Qualitative procedure: Provide a description of the steps you will take to identify, recruit, consent, collect data from and follow up participants, including how often data will be collected and by who.* *Quantitative procedure: Provide a description of the steps you will take to identify, recruit, consent, collect data from and follow up participants including how often data will be collected and by who.* **Sample size***Qualitative sample size: Provide a justification for the sample size you have chosen. This could include any practical considerations, budgetary constraints, data saturation, as appropriate.**Quantitative procedure: Provide a justification for the sample size you have chosen. This could be a sample size calculation, if applicable, considerations for precision, or justification related to a generalisable sample.* **Statistical analysis***Qualitative analysis: Provide a description of the statistical methods that will be used (e.g. coding (inductive/deductive), single or multiple coders).**Quantitative analysis: Provide a description of the statistical methods that will be used (e.g. descriptive statistics: count, percentage, frequency, median, mean, standard deviation; significance tests: student-tests, chi-square tests etc). It is good practice to express your results as a point estimate and 95% confidence intervals, as appropriate, and describe how you will calculate each.***A strength of mixed methods research projects is that they can examine an issue from multiple perspectives and develop a more complete understanding of an issue. How do you plan to combine the qualitative and quantitative components?** (Check all that apply)[ ]  I do not plan to combine the findings of the qualitative and quantitative components[ ]  Connecting (one type of data links with the other through the sampling frame e.g. a study that includes a survey and interviews, people who respond to the survey are subsequently invited to take part in the interview)[ ]  Building (one research component will inform the data collection of another component)[ ]  Merging (qualitative and quantitative data are brought together for the analysis and for comparison)[ ]  Embedding (Data collection and analysis linking data collection and analysis at multiple time points) |
| **Ethical Considerations** | *Consult the checklist at* [*Appendix A: Ethical Considerations Checklist*](#EthicalConsiderationsChecklist)*. If any risks are identified, indicate how they will be mitigated and/or addressed. Provide information on how informed consent will be obtained if applicable. Consider whether your study population proposes to include specific participants as outlined in Section 4 of the* [*National Statement on Ethical Conduct in Human Research (2007)*](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__1931)(the National Statement) *and address an ethical consideration specific to them. These include:** *Women who are pregnant and the human fetus*
* *Children and young people*
* *people in dependent or unequal relationships*
* *People highly dependent on medical care who may be unable to give consent*
* *People with a cognitive impairment, an intellectual disability, or a mental illness*
* *People who may be involved in illegal activities*
* *Aboriginal and Torres Strait Islander Peoples*
* *People in other countries*
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| **Governance**  | *Standardised answers have been provided to assist you completing this section in accordance with data management policies and guidelines. Please provide additional details or revise/delete as required.* **Data storage:** *NOTE: storage on portable media, laptops and desktop computer hard drives is not acceptable.*Electronic data will be stored on a physically secure NNSW LHD file server that is password protected. Hardcopy material will be stored in a secure file. **Data access:** *specify how data will be accessed by investigators.*Data and hardcopy material will only be accessible to the project team.**Data retention:** Records will be retained for a minimum of 5 years after project completion in accordance with the *State Records Act 1998* (NSW). **Data disposal**: Records will be deleted from the secure NNSW LHD file server 5 years post project completion. Hardcopy material will be securely destroyed or shredded.  |
| **Additional Material:** | *If required, provide a list of the study material(s) (e.g. Participant Information Statement, Consent Form, Survey)* |
| **Applicable National Safety and Quality Health Service Standards:** | *Select the Applicable NSQHS Standard/s. See:* [*https://www.safetyandquality.gov.au/standards/nsqhs-standards*](https://www.safetyandquality.gov.au/standards/nsqhs-standards)

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|[ ]  Clinical Governance Standard |[ ]  Partnering with Consumers Standard |
|[ ]  Preventing and Controlling Healthcare-Associated Infection Standard |[ ]  Medication Safety Standard |
|[ ]  Comprehensive Care Standard |[ ]  Communicating for Safety Standard |
|[ ]  Blood Management Standard |[ ]  Recognising and Responding to Acute Deterioration Standard |
|[ ]  Other:  |

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| **References:**  |  |

Ethical Considerations Checklist

This checklist is based on the [*HREC: Human Research Ethics Committees – Quality Improvement & Ethical Review: A Practice Guide for NSW* (GL2007\_020)](https://www1.health.nsw.gov.au/PDS/pages/doc.aspx?dn=GL2007_020)

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| Section 1: Issues that may require consent |
| 1. | The project involves direct contact with patients, consumers or members of the public |
|  | Direct contact with patients or families through phone calls or face-to-face interview may potentially create undue pressure or coercion, depending on how direct contact is planned. Patients or families may feel pressured firstly to participate, and secondly to respond in particular ways, depending on factors such as patient vulnerability or whether there is an ongoing treatment/care relationship. Patient surveys may legitimately ask about attitudes to aspects of care, but if these are not anonymous, may leave patients feeling compromised. | Choose an item. |
| 2. | The project poses additional risks or burdens to the patient beyond their routine care |
|  | Additional harms or risks may be physical harm, psychological disturbance, risk of spiritual or social harm, or distress. Tests, blood samples, or medical interventions additional to the patient’s routine clinical care will likely constitute burdens warranting express patient consent, as may persistent phone calls, additional visits to hospital, or lengthy or intrusive questionnaires. Potential exploitation of cultural knowledge or property is considered another harm. There have been instances where such information has been damaging to some cultural minorities, such as contributing to discriminatory attitudes and stigmatisation. | Choose an item. |
| 3. | The data to be collected is of a sensitive nature or application |
|  | Correspondence sent to a patient that includes sensitive health information could lead to a breach of confidentiality if such communication were to be read by another person.  | Choose an item. |
| 4. | The data will be used or available in such a way that may identify individuals |
|  | Data that allows for identification of a specific individual are referred to as ‘identified data’. Examples of identifiers are the individual’s name, date of birth, address, or diagnosis where the condition is rare. In very small data sets, even information such as a postcode may be an identifier. | Choose an item. |
| 5. | The activity requires use of health information for a valid “secondary purpose” and/ or falls within the ‘directly related purpose’ exemption |
|  | Health information is collected for the primary purpose to provide clinical care to the patient. All other uses of this health information are considered secondary uses (e.g. for research) and must be approved by an HREC or exempted from the requirements for HREC review (under specific conditions e.g. QA review pathway) for it to comply with the *Health Records and Information Privacy Act 2002* (NSW). Use of health information for a valid “secondary purpose” and/or falls within the ‘directly related purpose’ exemption includes using patient information for purposes related to the operations of the NSW health service and treatment of patients e.g. planning, safety and quality improvement activities and using information for quality assurance or clinical audit activities such as monitoring, evaluating and auditing the provision of a service. If it is unclear whether the activity is a ‘directly related purpose’, please contact the NNSWLHD Research Office or consult the [NSW Health Privacy Manual](https://www.health.nsw.gov.au/policies/manuals/Pages/privacy-manual-for-health-information.aspx) ([Section 11.2](https://www.health.nsw.gov.au/policies/manuals/Documents/privacy-section-11.pdf), Version 3, March 2015). | Choose an item. |
| If the response to statements 1 to 4 is “**true**” OR statement 5 is “false”, you will need to include in your project proposal a description of how you intend to gain consent, and you will need to develop a **Participant Information Statement** and where applicable a **Consent Form** (see [template](https://nnswlhd.health.nsw.gov.au/wp-content/uploads/NNSWLHD_Participant-Information-Statement-and-Consent-Form.docx)). |

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| Section 2: Privacy and Confidentiality |
| 6. | There is no process for de-identification of data. |
|  | Data should be de-identified before being given to third parties who would not normally have access to them.  | Choose an item. |
| 7. | Access to personal information will extend beyond those who are members of the clinical care team, or to others who normally do not have access to the patient’s record, or to other data sets. |
|  | The ‘clinical care team’ refers to the group of health professionals involved in provision of clinical care including nursing and medical clinicians, and allied health professionals. Student health professionals enrolled in recognised teaching institutions may have access to health records with the approval and direction of their supervisor (or the relevant Head of Department) if that access is sought in respect of their education program at the health facility. | Choose an item. |
| 8. | The project involves rare conditions or a small community. |
|  | Where patient numbers are limited or the diagnosis is rare, this may inadvertently result in the patient being identified, even where the data have been de-identified in the usual manner. Quality Activities that combine groups of similar patients from small units may assist in maintaining confidentiality, where this is feasible. See further information on [case study/series](https://nnswlhd.health.nsw.gov.au/human-research-ethics-and-governance/what-is-research-governance/). | Choose an item. |
| 9. | Data will be selected or identified by: Aboriginal or Torres Strait Islander status; or Ethnic, religious or minority group. |
|  | Quality Activities amongst religious, ethnic, or minority groups should be undertaken following appropriate consideration of cultural difference, as relevant to the activity. Some ethical issues associated with a Quality Activity may need to be considered in a broader context than the individual patient context, for example the notion of ‘community privacy’ often applies in Aboriginal communities. | Choose an item. |
| 10. | Data will be collected beyond that which is normally collected in routine care. |
|  | No additional comment.  | Choose an item. |
| If the response to any of the above statements is “**true**”, you will need to provide information in your project proposal including a description of the consent process. |

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| Section 3: Other Implications |
| 11. | The project uses ‘new’ interventions, protocols or equipment. |
|  | Where new knowledge is being generated, this may create a greater potential risk of harm to subjects. This is more applicable to research but may also apply to some Quality Activities where new or alternate clinical interventions are undertaken. ‘New’ interventions refer to those not previously used for this purpose or in this institution. See also Model Policy for the Safe Introduction of New Interventional Procedures Into Clinical Practice - PD2005\_333. | Choose an item. |
| 12. | The project will involve allocation of patients to groups to enable comparisons. |
|  | Randomisation, or allocation of patients to groups, to enable comparison of interventions is indicative of a research methodology that is likely to warrant review by a Human Research Ethics Committee (HREC). Consult the NNSW LHD Research Office for further guidance by email: NNSWLHD-Ethics@health.nsw.gov.au or telephone: (02) 6672 0269  | Choose an item. |
| 13. | The project will involve genetic tests/testing. |
|  | Genetic testing may have an impact on not only the individual being tested, but also other family members. Quality Activities involving genetic information need informed consent, given the sensitive nature of the information and its potential implication. | Choose an item. |
| 14. | The project may potentially infringe the rights, privacy or professional reputation of carers, health professionals or institutions. |
|  | There is increasing interest in the comparison of patient outcomes or other performance indicators within or across units, departments or individual clinicians. However, these comparisons must be against agreed benchmark standards, and with appropriate consideration of the variables impacting on outcomes and performance, such as patient acuity. Where use of comparative data between individual clinicians or institutions occurs, this should be clearly grounded within the institution’s clinical governance system. There is a general obligation to feedback results of Quality Activities to health professionals who have been directly involved in a Quality Activities or affected locally by its results. There should also be consideration given to providing results of Quality Activities to other participant groups. | Choose an item. |
| 15. | The project involves use of placebo. |
|  | Any project involving randomisation or other means of allocation to one of two or more treatment options requires HREC review. | Choose an item. |
| If the response to any of the above statements is “**true**”, you will need to provide more information and it is highly likely you will need full Ethics Committee approval for your project. Consult the NNSW LHD Research Office for further guidance by email: NNSWLHD-Ethics@health.nsw.gov.au or telephone: (02) 6672 0269  |

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| 16. | The project is likely to generate data that may lead to publication. |
|  | Many professional journals require evidence of ethical review[[1]](#footnote-1) before Quality Activity results will be published, especially where identifiable or sensitive data are audited, or potential harms or burdens exist. This also applies where the results of the Quality Activities are for publication as a conference abstract. Some, in particular international, journals may apply different standards for ethical review. Intending authors should explore this on an individual basis.  | Choose an item. |

1. Ethical review: Review of research by an HREC or other body (see: [The National Statement](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__1931)). [↑](#footnote-ref-1)