Guidelines for study design and ethical approval

1. Laboratory and clinical research should be driven by a protocol: pilot studies should have a written protocol.
2. Research protocol should seek to specific questions, rather than just collect data.
3. Protocols should be carefully agreed by all contributors and collaborators, including the participants.
4. The final protocol should form part of the research record.
5. Statistical issues should be study considered early in design, including power calculation to ensure there are correct numbers of participants in the study.
6. Formal and documented ethical approval is required for all studies on human, human tissues and medical records.
7. Use of human tissues in research should conform to the highest ethical standards.
8. Fully informed consent should always be sought.
9. Animal experiments require full compliance with local, national, ethical and regulatory principles and local licensing arrangements.
10. Formal supervision, usually the responsibility of the principal investigator, should be provided for all research projects, this must include quality control and frequent review of all records and primary outputs.
11. Upon receiving the research, Rs 200/- has to be deposited for seeking ethical clearance and forms which are to be collected from ethical office.
12. Candidate has to submit following documents to seek ethical clearance:
    a. Application for plea to ethical committee certificate
    b. Synopsis or briefing of the research proposed with detailed material and methods
    c. Ethical forms
13. File will then be forwarded to one of ethical committee member for review. The candidate can be asked to present their synopsis in the meeting of ethical committee, the date of which will be informed prior. If changes are required, the candidate will be asked to make corrections and resubmit the corrected research again to ethical committee office. If found satisfactory, the ethical clearance certificate will be issued to the candidate.
14. Every research study involving human subjects must be registered on a publicly accessible database before recruitment of the first subject. All clinical research involving human

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participants including any intervention such as drugs, surgical procedures, devices, biomedical, educational or behavioural research, public health intervention studies, observational studies, implementation research and preclinical studies of experimental therapeutics and preventives may be registered prospectively with the CTRI.

15. Trial registration involves providing information regarding the study, investigators, sites, sponsor, ethics committees, regulatory clearance, disease, types of study, methodologies, outcomes etc.
16. Registration of research in CTRI ensures that more complete, authenticated, readily available data on research is available publicly. This improves transparency, accountability and accessibility.

Agenda of ethical committee meeting:

- All proposals have to undergo full committee review and decision will be taken at full committee meeting
- The researcher may be called in to present a proposal or provide clarifications on study protocol that has been submitted for review.
- All members of EC present in the room have the right to vote/express their decision and should exercise this right.
- The decision must be taken by majority vote and should be recorded. Any negative opinion should also be recorded with reasons.
- The decision may be given in following format:
    - Approved- with or without suggestions or comments
    - Revision with minor modifications
    - Revision with major modifications- this will be presented again in next EC meeting
    - Not approved- clearly stating the reasons for not approving.
- Minutes of meetings to be noted.
- All documentation and communication of EC will be filed, dated and preserved in EC office.
- All active and inactive files will be appropriately labeled and preserved
- All records will be kept confidential.

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Subject: Subscription of anti pliagrism software

SDCRI Management has decided to procure Urkund: Anti-Plagiarism Software using it to check the copying of another person's material and using such copied material. Theses and Dissertations, manuscripts received for publication as well as other documents produced by the University from time to time will be checked by using this software. Keeping in view the importance and usefulness of the software, honorable VC has accorded expenditure sanction for Rs. 79,629.00 inclusive GST () 8%) in order to subscribe its Licence for 12 months (Academic) for a maximum of I00documents.

It is submitted that they have provided us Username" and "Password" to access the URKUND Software. A comprehensive training in the operation of Software has been provided.

A copy of invoice to. 20 I 7/hG/l. 106 dated 09 March 2018 for Rs. 79,629.00 claiming subscription charges to their Licence for 12 months (Academic) for a maximum of 100 documents has been received.

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