Ethical Approval Form

This checklist should be completed for every research project that involves human participants. It will be used by the module tutor to identify whether a fuller application for ethics approval needs to be submitted or whether the research can proceed without this.

Section I: Project Details

1. Project title:	Clinical therapeutic effects of AO/ASIF clavicle hook plate on distal clavicle fractures and acromioclavicular joint dislocations
No. of participants	100
Estimated start date	January 2012
Estimated end date	January 2013

Section II: Applicant Details

2. Name of researchers (applicant): Qingjun Dou

Section III: Module Tutors/Dissertation Supervisors Only

Please tick the appropriate boxes. The study should not begin until all boxes are ticked:

The topic merits further research ☒

The participant information sheet or leaflet is appropriate ☒

The procedures for recruitment and obtaining informed consent are appropriate ☒

Section IV: All Research Applicants

Please outline below whether or not your research raises any particular ethical issues and how you plan to address these issues.

Are you using a Participant Information and Informed Consent Form? YES ☒ NO ☐

Have you considered the risks associated with this project? YES ☒ NO ☐

Now proceed to the Research Ethics Checklist

Section V: Research Ethics Checklist

Please answer each question by ticking the appropriate box:

	YES	NO
1. Does the study involve participants who are particularly vulnerable or unable to give informed consent? (e.g. children, people with learning disabilities, your own students)	☐	☒
2. Will the study require the co-operation of a gatekeeper for initial access to the groups or individuals to be recruited? (e.g. students at school, members of self-help group, residents of nursing home)	☐	☒
3. Will it be necessary for participants to take part in the study without their knowledge and consent at the time? (e.g. covert observation of people in non-public places)	☐	☒
4. Will the study involve discussion of sensitive topics (e.g. sexual activity, drug use)?	☐	☒

5. Are drugs, placebos or other substances (e.g. food substances, vitamins) to be administered to the study participants or will the study involve invasive, intrusive or potentially harmful procedures of any kind?	☐	☒
6. Will blood or tissue samples be obtained from participants?	☐	☒
7. Is pain or more than mild discomfort likely to result from the study?	☐	☒
8. Could the study induce psychological stress or anxiety or cause harm or negative consequences beyond the risks encountered in normal life?	☐	☒
9. Will the study involve prolonged or repetitive testing?	☐	☒
10. Will financial inducements (other than reasonable expenses and compensation for time) be offered to participants?	☐	☒
11. Measures have been taken to ensure confidentiality, privacy and data protection where appropriate	☒	☐

Any significant change in the question, design or conduct over the course of the research should be notified to the Tutor and may require a new application for ethics approval.

Signatures		Date
Principal Investigator/Students	…Qingjun Dou……	…3rd Jan 2012…
(All researchers must sign)	…Xiaofeng Ren……	…3rd Jan 2012…

Supervisor/module leader/research ethics officer (where appropriate) ……Bin Zhang……