Participant Study Number

TRIAL CONSENT FORM
C-GALL

By INITIALLING each box and signing this form:

Please INITIAL all boxes

1) I confirm that I have

a) read the Information Sheet about the C-GALL trial (Version number , date). ☐

b) I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2) I agree that

a) my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

b) relevant sections of my medical notes and data collected during the trial may be looked at by individuals directly involved in the trial, from the University of Aberdeen or from the NHS Boards or Trusts, where it is relevant to my taking part in this research. I give permission for these individuals to have access to them. ☐

c) relevant data collected during the trial together with personal contact details will be held confidentially and securely by the University of Aberdeen. I agree that the study co-ordinators can use my contact details to send me study questionnaires and to contact me by <<phone or post or email or text>> ☐

d) relevant information may be collected from my hospital medical notes, held and maintained by NHS bodies such as Office of National Statistics (ONS), NHS Digital, and other relevant government bodies and may be used to provide information about my health status. ☐

I agree to take part in the study ☐

OPTIONAL (Please indicate your preference by initialling the Y [Yes] or N [No] box.)

I agree to my General Practitioner being informed of my participation in this study. Y ☐ N ☐

I understand that I may be contacted in the future for long-term follow-up. Y ☐ N ☐

I understand agree that the information collected about me may be shared anonymously with other researchers to support future research, including those out with the UK. Y ☐ N ☐

I am willing to be contacted in the future about participating in other relevant research. Y ☐ N ☐

Your signature (participant)	Name in BLOCK capitals	Date

To be completed by the local team member taking consent

I confirm that I have explained to the person named above, the nature and purpose of the study and the procedures involved.

Signature	Name in BLOCK capitals	Date

C-GALL Office,, Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit, University of Aberdeen, Scotland AB25 2ZD; Tel 01224 438089; Fax 01224 438165; cgall@abdn.ac.uk

Copies: ***White sent to trial office in Aberdeen; pink to participant, green to site file and yellow to be filed with hospital notes.***

C-GALL Summary

Design: Parallel group, multicentre patient randomised superiority trial with 24 months follow-up. Embedded qualitative research will identify any challenges during an internal pilot phase.

Setting: Secondary care

Participants: Adults with symptomatic uncomplicated gallstone disease who are referred to a secondary care setting and considered suitable for cholecystectomy.

Exclusion criteria: Unable to consent, medically unfit for surgery, current pregnancy, previous major upper abdominal surgery (open), common bile duct stones, acute gallstone pancreatitis, obstructive jaundice, empyema of the gallbladder, suspicion of gallbladder cancer, perforated gallbladder, haemolytic disease.

Health technologies being assessed: (i) Laparoscopic cholecystectomy: the current standard surgical procedure for the management of symptomatic gallstone disease. The gall bladder is removed with the stones within it using keyhole techniques (laparoscopy). The procedure is undertaken under a general anaesthetic. (ii) Medical management: involves the prescription of analgesics to relieve the biliary pain. Typical therapy includes paracetamol, antispasmodics (e.g. Buscopan), nonsteroidal anti-inflammatory drugs NSAIDs (e.g. ibuprofen etc), and narcotic analgesics (e.g. opiates) together with generic lifestyle advice.

Primary outcomes: Patient outcome measure - quality of life as measured by area under the curve (AUC) at up to 18 months post-randomisation using the SF-36 bodily pain domain (AUC measures at 3, 9, 12 and 18 months). Economic outcome measure - incremental cost per QALY.

Secondary outcomes: Condition specific quality of life (CSQ); SF-36 domains (excluding bodily pain); complications; need for further treatment; persistent symptoms; health care resource use; costs.

Data collection: The patient reported outcomes (SF-36; CSQ) will be assessed by participant completed questionnaires at baseline and 3, 9, 12, 18- and 24-months post randomisation and six monthly thereafter till the end of the trial. A case report form (CRF) at the time of surgery provides details of the operative procedures, complications and resource use in hospital. Costs of the initial intervention procedures will be estimated from resource use data recorded on the case report forms coupled with routine unit cost data. Costs associated with subsequent contacts with primary and secondary care (due to symptomatic gallstones) will be estimated from patient questionnaires at 3, 9, 12, 18- and 24-months post randomisation and six monlthy thereafter till the end of the trial and checked at source. QALYs will be estimated from patients' responses to the SF-36.

Sample size: To detect a 0.33 of a standard deviation difference in the area under the curve (AUC) of the SF-36, 90% power with alpha 5%, 194 participants per group (388 total) are required. Such a difference in generic health status is considered clinically relevant and in terms of treatment effect size, in the small to medium range as observed in other clinical studies. To allow for the anticipated approximately 10% of participants for whom outcome data is completely missing, and therefore the AUC cannot be calculated, it is proposed to randomise 430 participants.

C-GALL

Consent Form for Audio-recording (Clinical Team Member)

	Please initial boxes
1. I agree to the consultations being audio recorded.	
2. I understand that anonymised quotations from this discussion may be used for presentations and publications.	

By signing this form I agree that I have been given the opportunity to discuss this study and that my participation is voluntary.

_____	_____	_____
Name of participant (in BLOCK CAPITALS)	Date	Signature
_____	_____	_____
Name of researcher taking consent (in BLOCK CAPITALS)	Date	Signature

C-GALL Office,, Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit, University of Aberdeen, Scotland AB25 2ZD; Tel 01224 438089; Fax 01224 438165; cgall@abdn.ac.uk

Copies: Original for research site file; 1 each for participant and trial office

C-GALL

Consent Form for Patient Interview

Participant Study Number ☐☐-☐☐☐

Name of Local Principal Investigator [NAMExxx]……..

1. I confirm that I have read and understand the information sheet dated……version…….. for the above study. I have had the opportunity to consider the information and ask questions, and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary, and that I am free to withdraw at any time, without giving a reason, without my medical care or legal rights being affected. ☐

3. I agree to the discussions being audio recorded. ☐

4. I understand that anonymised quotations from this interview may be used for presentations and publications. ☐

5. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the University of Aberdeen, from regulatory authorities or from the NHS Board/Trust, where it is relevant to my taking part in this research. I give permission for these individuals to access to my data. ☐

6. I understand that I might be approached again and invited to participate in a further discussion. I also understand that any further participation is optional, and that I can ask to be removed from the invitation list at any time. ☐

7. I agree to take part in an interview for the above study. ☐

_____	_____	_____
Name of participant	Date	Signature
_____	_____	_____
Name of researcher taking consent	Date	Signature

C-GALL Office,, Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit, University of Aberdeen, Scotland AB25 2ZD; Tel 01224 438089; Fax 01224 438165; cgall@abdn.ac.uk

Copies: Original for research site file; 1 each for participant and trial office

C-GALL
Interview Consent Form

Participant Study Number ☐☐-☐☐☐

1. I confirm that I have read and understand the information sheet dated……version…….. for the above study. I have had the opportunity to consider the information and ask questions, and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary, and that I am free to withdraw at any time, without giving a reason. ☐

3. I agree to the discussions being audio recorded. ☐

4. I understand that anonymised quotations from this interview may be used for presentations and publications. ☐

5. I understand that data collected during the study, may be looked at by individuals from the University of Aberdeen, from regulatory authorities or from the NHS Board/Trust, where it is relevant to my taking part in this research. I give permission for these individuals to access to my data. ☐

6. I understand that I might be approached again and invited to participate in a further discussion. I also understand that any further participation is optional, and that I can ask to be removed from the invitation list at any time. ☐

7. I agree to take part in an interview for the above study. ☐

_____	_____	_____
Name of participant	Date	Signature
_____	_____	_____
Name of researcher taking consent	Date	Signature

C-GALL Office,, Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit, University of Aberdeen, Scotland AB25 2ZD; Tel 01224 438089; Fax 01224 438165; cgall@abdn.ac.uk
Copies: Original for research site file; 1 each for participant and trial office