FiCTION 07/44/03: STUDY DOCUMENTATION

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ETHICAL APPROVAL LETTERS

EoSRES

NHS SCOTLAND

East of Scotland Research Ethics Service (EoSRES) REC 1
(formerly Tayside Committee on Medical Research Ethics A/B)
Tayside Medical Sciences Centre (TASC)
Residency Block C, Level 3
Ninewells Hospital & Medical School
George Pirie Way
Dundee DD19SY

Professor Jan Clarkson
Director of the Effective Dental Practice Programme
University of Dundee
School of Dentistry,
Park Place
Dundee DD1 4HR

Date: 30 July 2012
Your Ref:
Our Ref: LR/**12/ES/0047**
Enquiries to: Mrs Lorraine Reilly
Extension: Ninewells extension: 40099
Direct Line: 01382 740099
Email: eosres.tayside@nhs.net

Dear Professor Clarkson

Study Title: **FiCTION - Filling Children's Teeth: Indicated or Not?**
REC reference: **12/ES/0047**
Protocol number: **NCTU: ISRCTN77044005**

Thank you for your letter of 30 July 2012. I can confirm the REC has received the documents listed below as evidence of compliance with the approval conditions detailed in our letter dated 20 July 2012. Please note these documents are for information only and have not been reviewed by the committee.

Documents received

The documents received were as follows:

Document	Version	Date
Other: Email correspondence		30 July 2012
Participant Information Sheet: Parent - clean copy	2.0	30 July 2012
Participant Information Sheet: Parent - tracked changes	2.0	30 July 2012

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

12/ES/0047: ***Please quote this number on all correspondence***

Yours sincerely
L. Reilly
Mrs Lorraine Reilly
Senior Co-ordinator

Email: eosres.tayside@nhs.net

Copy to: Mr Chris Speed, Newcastle Clinical Trials Unit, University of Newcastle
Ms Shona Haining, Newcastle PCT
NHS Tayside R&D Office

POSITIVE ABOUT DISABLED PEOPLE

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Dear Professor Clarkson

Study Title:	**FiCTION - Filling Children's Teeth: Indicated or Not?**
REC reference:	**12/ES/0047**
Protocol number:	**NCTU: ISRCTN77044005**
Amendment number:	**AM01 (for REC reference only)**
Amendment date:	**25 July 2012**

Thank you for your letter of 25 July 2012, notifying the Committee of the above amendment.

The Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

Documents received

The documents received were as follows:

Document	Version	Date
Questionnaire: Health Economics Questions for Parents Q9-Q22 (tracked changes)	2.0	25 July 2012
Questionnaire: Health Economics Questions for Parents Q9-Q22 (clean version)	2.0	25 July 2012
Notification of a Minor Amendment	AM01	25 July 2012

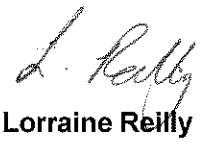
Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

POSITIVE ABOUT DISABLED PEOPLE

12/ES/0047:	***Please quote this number on all correspondence***

Yours sincerely



Mrs Lorraine Reilly
Senior Co-ordinator

Email: eosres.tayside@nhs.net

Copy to: Mr Chris Speed, Newcastle Clinical Trials Unit, University of Newcastle
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Dundee DD19SY

Professor Jan Clarkson
Director of the Effective Dental Practice Programme
University of Dundee
School of Dentistry,
Park Place
Dundee
DD1 4HR

Date:	24 July 2012
Your Ref:	
Our Ref:	**LR/12/ES/0047**
Enquiries to:	Mrs Lorraine Reilly
Extension:	Ninewells extension: 40099
Direct Line:	01382 740099
Email:	lorraine.reilly@nhs.net

Dear Professor Clarkson

Study Title:	**FiCTION - Filling Children's Teeth: Indicated or Not?**
REC reference:	**12/ES/0047**
Protocol number:	**NCTU: ISRCTN77044005**

Thank you for your letter of 16 July 2012, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered by a sub-committee of the REC at a meeting held on 20 July 2012. A list of the sub-committee members is attached.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

- With regards to Provisional Opinion letter dated 25 June 2012, No.2 The Participant Information Sheet (PIS) should be amended as follows: Bullet point 3 has not been answered - Under 'will anyone else know my child is in this study?' - the Committee required further clarification regarding '...people who have the need or right will know you are in the study' a suggestion would be to change text to '...the researchers and anyone involved in your clinical care will know you are in the study'.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Confirmation should also be provided to host organisations together with relevant documentation.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Advertisement	1.0	02 April 2012
Covering Letter		02 April 2012
Evidence of insurance or indemnity		17 August 2011
Evidence of insurance or indemnity		27 April 2012
Evidence of insurance or indemnity		28 September 2011
Evidence of insurance or indemnity		05 August 2011
Evidence of insurance or indemnity		11 July 2011
GP/Consultant Information Sheets	1.0	02 April 2012
Investigator CV		29 March 2012
Letter from Sponsor		27 April 2012
Letter from Statistician		29 March 2012

Letter of invitation to participant	1.0	02 April 2012
Other: Funding Letter		02 March 2009
Other: Childs Membership Card	1.0	02 April 2012
Other: Clinical Protocol.		
Participant Consent Form: Child	1.0	02 April 2012
Participant Consent Form: Parent: Clean	1.1	29 June 2012
Participant Consent Form: Parent: Tracked Changes	1.1	29 June 2012
Participant Information Sheet: Participant Information Booklet	1.0	03 May 2012
Participant Information Sheet: Parent: Clean	1.1	29 June 2012
Participant Information Sheet: Parent: Tracked Changes	1.1	29 June 2012
Participant Information Sheet: Childrens: Clean	1.1	29 June 2012
Participant Information Sheet: Childrens: Tracked Changes	1.1	29 June 2012
Protocol	1.0	02 April 2012
Questionnaire: Dental Discomfort Questionnaire	1.0	02 April 2012
Questionnaire: MCDASf Scale Children	1.0	02 April 2012
Questionnaire: Parent Perception Questionnaire	1.0	02 April 2012
Questionnaire: Health Economics Questions to Parents	1.0	02 April 2012
Questionnaire: Pain Items to Child	1.0	02 April 2012
Questionnaire: Worry & Pain Items to Parents	1.0	02 April 2012
Questionnaire: Worry Items to Child	1.0	02 April 2012
REC application	103239/320708/1/231	04 May 2012
Response to Request for Further Information		16 July 2012
Response to Request for Further Information		03 July 2012
Summary/Synopsis	1.0	02 April 2012

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

12/ES/0047:	***Please quote this number on all correspondence***

Yours sincerely

L Reilly

Dr Carol Macmillan
Chair

Email: lorraine.reilly@nhs.net

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments.
"After ethical review – guidance for researchers"

Copy to: Mr Chris Speed, Newcastle Clinical Trials Unit, University of Newcastle
Ms Shona Haining, Newcastle PCT
NHS Tayside R&D Office

East of Scotland Research Ethics Service REC 1

Attendance at Sub-Committee of the REC meeting on 20 July 2012

Committee Members:

Name	Profession	Present	Notes
Dr Carol Macmillan	Consultant Anaesthetist	Yes	Chair
Mrs Jacqueline Dunlop	Macmillan Genetic Counsellor	Yes	
Mr John Macleod	Retired	Yes	

Also in attendance:

Name	Position (or reason for attending)
Mrs Lorraine Reilly	Senior Co-ordinator

NHS
National Research Ethics Service

RESEARCH IN HUMAN SUBJECTS OTHER THAN CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS

After ethical review – guidance for sponsors and investigators

This document sets out important guidance for sponsors and investigators on the conduct and management of research with a favourable opinion from a NHS Research Ethics Committee. Please read the guidance carefully. A failure to follow the guidance could lead to the committee reviewing its opinion on the research.

1. Further communications with the Research Ethics Committee

1.1 Further communications during the research with the Research Ethics Committee that gave the favourable ethical opinion (hereafter referred to in this document as "the Committee") are the personal responsibility of the Chief Investigator.

2. Commencement of the research

2.1 It is assumed that the research will commence within 12 months of the date of the favourable ethical opinion.

2.2 The research must not commence at any site until the local Principal Investigator (PI) or research collaborator has obtained management permission or approval from the organisation with responsibility for the research participants at the site.

2.3 Should the research not commence within 12 months, the Chief Investigator should give a written explanation for the delay

2.4 Should the research not commence within 24 months, the Committee may review its opinion.

3. Duration of ethical approval

3.1 The favourable opinion for the research generally applies for the duration of the research. If it is proposed to extend the duration of the study as specified in the application form, the Committee should be notified.

3.2 Where the research involves the use of "relevant material" for the purposes of the Human Tissue Act 2004, authority to hold the material under the terms of the ethical approval applies until the end of the period declared in the application and approved by the Committee.

4. Progress reports

4.1 Research Ethics Committees are expected to keep a favourable opinion under review in the light of progress reports and any developments in the study. The Chief Investigator should submit a progress report to the Committee 12 months after the date on which the favourable opinion was given. Annual progress reports should be submitted thereafter.

4.2 Progress reports should be in the format prescribed by NRES and published on the website (see www.nres.npsa.nhs.uk/applicants/after-ethical-review/).

4.3 The Chief Investigator may be requested to attend a meeting of the Committee or Sub-Committee to discuss the progress of the research.

5. Amendments

5.1 If it is proposed to make a substantial amendment to the research, the Chief Investigator should submit a notice of amendment to the Committee.

5.2 A substantial amendment is any amendment to the terms of the application for ethical review, or to the protocol or other supporting documentation approved by the Committee that is likely to affect to a significant degree:

(a) the safety or physical or mental integrity of the trial participants
(b) the scientific value of the trial
(c) the conduct or management of the trial.

5.3 Notices of amendment should be in the format prescribed by NRES and published on the website, and should be personally signed by the Chief Investigator. The agreement of the sponsor should be sought before submitting the notice of amendment.

5.4 A substantial amendment should not be implemented until a favourable ethical opinion has been given by the Committee, unless the changes to the research are urgent safety measures (see section 7). The Committee is required to give an opinion within 35 days of the date of receiving a valid notice of amendment.

5.5 Amendments that are not substantial amendments ("minor amendments") may be made at any time and do not need to be notified to the Committee.

6. Changes to sites

Management permission (all studies)

6.1 For all studies, management permission should be obtained from the host organisation where it is proposed to:

- include a new site in the research, not included in the list of proposed research sites in the original REC application
- appoint a new PI or Local Collaborator at a research site
- make any other significant change to the conduct or management of a research site.

In the case of any new NHS site, the Site-Specific Information (SSI) Form should be submitted to the R&D office for review as part of the R&D application.

Site-specific assessment (where required)

6.2 The following guidance applies only to studies requiring site-specific assessment (SSA) as part of ethical review.

6.3 In the case of *NHS/HSC sites*, SSA responsibilities are undertaken on behalf of the REC by the relevant R&D office as part of the research governance review. The Committee's favourable opinion for the study will apply to any new sites and other changes at sites provided that management permission is obtained. There is no need to notify the Committee (or any other REC) about new sites or other changes, or to provide a copy of the SSI Form.

6.4 Changes at *non-NHS sites* require review by the local REC responsible for site-specific assessment (SSA REC). Please submit the SSI Form (or revised SSI Form as appropriate) to the SSA REC together with relevant supporting documentation. The SSA REC will advise the main REC whether it has any objection to the new site/PI or other change. The main REC will notify the Chief Investigator and sponsor of its opinion within a maximum of 35 days from the date on which a valid SSA application has been received by the SSA REC.

Studies not requiring SSA

6.5 For studies designated by the Committee as not requiring SSA, there is no requirement to notify the Committee of the inclusion of new sites or other changes at sites, either for NHS or non-NHS sites. However, management permission should still be obtained from the responsible host organisation (see 6.1 above).

7. Urgent safety measures

7.1 The sponsor or the Chief Investigator, or the local Principal Investigator at a trial site, may take appropriate urgent safety measures in order to protect research participants against any immediate hazard to their health or safety.

7.2 The Committee must be notified within three days that such measures have been taken, the reasons why and the plan for further action.

8. Serious Adverse Events

8.1 A Serious Adverse Event (SAE) is an untoward occurrence that:

(a) results in death
(b) is life-threatening
(c) requires hospitalisation or prolongation of existing hospitalisation
(d) results in persistent or significant disability or incapacity
(e) consists of a congenital anomaly or birth defect
(f) is otherwise considered medically significant by the investigator.

8.2 A SAE occurring to a research participant should be reported to the Committee where in the opinion of the Chief Investigator the event was related to administration of any of the research procedures, and was an unexpected occurrence.

8.3 Reports of SAEs should be provided to the Committee within 15 days of the Chief Investigator becoming aware of the event, in the format prescribed by NRES and published on the website.

8.4 The Chief Investigator may be requested to attend a meeting of the Committee or Sub-Committee to discuss any concerns about the health or safety of research subjects.

8.5 Reports should not be sent to other RECs in the case of multi-site studies.

9. Conclusion or early termination of the research

9.1 The Chief Investigator should notify the Committee in writing that the research has ended within 90 days of its conclusion. The conclusion of the research is defined as the final date or event specified in the protocol, not the completion of data analysis or publication of the results.

9.2 If the research is terminated early, the Chief Investigator should notify the Committee within 15 days of the date of termination. An explanation of the reasons for early termination should be given.

9.3 Reports of conclusion or early termination should be submitted in the form prescribed by NRES and published on the website.

10. Final report

10.1 A summary of the final report on the research should be provided to the Committee within 12 months of the conclusion of the study. This should include information on whether the study achieved its objectives, the main findings, and arrangements for publication or dissemination of the research including any feedback to participants.

11. Review of ethical opinion

11.1 The Committee may review its opinion at any time in the light of any relevant information it receives.

11.2 The Chief Investigator may at any time request that the Committee reviews its opinion, or seek advice from the Committee on any ethical issue relating to the research.

STUDY LETTER OF INVITATION: CHILDREN AND PARENTS

Printed on Practice headed paper

Dear **<name of parent/guardian>**

I am writing to you to ask you and **<name of child>** to take part in a further small part of the FiCTION study, about the best way to look after children's teeth, that **<name of child>** is already participating in.

I have included two information sheets for you – one about what we are asking **<name of child>** to do and one about what we are asking you to do. I have also included an information sheet for **<name of child>**. These tell you all about this part of the research study, why we are doing it and how we are doing it. We would very much like you and **<name of child>** to look at these information sheets and have a talk with each other about taking part.

I have also included an expression of interest form. If you and **<name of child>** decide that you would like to take part or if you would like to find out more before deciding, please complete and return this form in the stamped addressed envelope provided.

A researcher from the study team will then contact you and **<name of child>** by telephone to chat about you taking part and answer any questions you have. If you and **<name of child>** then decide that you would like to take part the researcher will organise a time and place to come and speak to you both.

We are looking for around 25 children and 25 parents/guardians to take part in this part of the FiCTION study. If we receive more expression of interest forms than this we may not contact everyone who returned the forms.

Thank you for taking the time to read this letter and for considering taking part.

Yours sincerely

<GDP to sign>

TOPIC GUIDE: CHILDREN AND PARENTS

A Qualitative Exploration of the Acceptability of the Three Treatment Strategies for Child Participants and Parents/Guardians – Topic Guide

Ayala & Elder (2011): *Acceptability refers to determining how well an intervention will be received by the target population and the extent to which the new intervention or its components might meet the needs of the target population and organizational setting.*

Sidani – presentation: *Acceptability refers to participants' perception of intervention as appropriate in addressing health-related problem they experience, effective, convenient or easy to apply in daily life, with minimal side effects.*

Sidani et al. (2009): *The attributes commonly found to shape treatment preferences are: appropriateness in addressing the presenting clinical problem, suitability to individual life style, convenience, and effectiveness in managing the clinical problem (Lambert et al., 2004; Miranda, 2004; Tacher, Morey, & Craighead, 2005). A treatment option is acceptable if perceived as reasonable and appropriate for managing the problem, non-intrusive, consistent with lifestyle, easy to apply, and effective (Tarrier, Liversidge, & Gregg, 2006).*

Tarrier, Liverside & Gregg (2006): *Participants rated each therapy on a rating scale of 1 (low/poor) to 9 (high/excellent) for each of the following dimensions: Acceptability; Suitability; Tolerability; Expectation of positive benefit; Credibility; Efficacy. Appropriateness; Reasonableness; Justifiable; and, would cause Discomfort (this was reversed scored). Participants were then asked to rank the 14 treatments in order of their personal preference.*

Aim: to explore the acceptability of the three treatment strategies for patients and parents		
Objectives	**Things to probe with participants**	**Things to probe with parents**
1. To explore participants' and parents' experiences of the three treatment strategies	• What treatment did they receive? • What did they like about it? *(probe: procedures used, how much they looked forward to appointments, how they would feel if they were told they had more tooth decay and had to have the same treatment again)* • What did they not like so much about it? *(probe: discomfort, side effects, anything that made them worried or concerned, how much they wanted the treatment to be over as soon as*	• What did they like about the treatment their child received? *(probe: procedures used)* • What did they not like so much about it? *(probe: child's discomfort, side effects, anything that made them worried or concerned, how they would feel if they were told that their child had more tooth decay and had to have the same treatment again, how they found the radiographs/fillings/extractions/injections/metal crowns/having nothing done)*

Objectives	Things to probe with participants	Things to probe with parents
	possible, how they would feel if they were told that they had to have the same treatment again, how they found the radiographs/fillings/extractions/injections/metal crowns/having nothing done) • Did the dentist and dental team members understand and address their concerns and worries? • When the treatment was explained to them did they understand what was going to happen? • Did they think it would be an effective way to address their tooth decay? • Do they think it was an appropriate way to address their tooth decay? • Is it how they expected the dentist to treat their tooth decay? • Do they think it has it been effective in addressing their tooth decay? • Do they think there were any disadvantages in following the method of treatment? • What did they learn? *(probe: new knowledge and skills to look after their teeth)* • Can they use what they learned to improve their teeth? • Are they glad they had the treatment they did? Why? How do they feel about visits to the dentist? Has this changed since taking part in FiCTION?	• Did the dentist and dental team members understand and address their concerns and worries? • When the treatment was explained to them did they understand what was going to happen? • Did they think it would be an effective way to address their child's tooth decay? • Do they think it was an appropriate way to address their child's tooth decay? • Is it how they expected the dentist to treat their child's tooth decay? • Do they think it has it been effective in addressing their child's tooth decay? • Do they think there were any disadvantages in following the method of treatment? • What did they learn? *(probe: new knowledge/skills to look after their child's teeth)* • Can they use what they learned to improve their child's teeth? • Are they glad their child had the treatment they did? Why? • What is their child's attitude to dental visits? Has this changed since taking part in FiCTION?
2. To explore how the management of dental caries impacts upon the daily lives of the	• Was it disruptive to their life to have this treatment? In what way? *(probe: time off school, usual activities)* • How easy was it to fit the best practice prevention part of the treatment into their daily life?	• Was it disruptive to the family for the child to have this treatment? In what way? *(probe: time off school, work, usual activities, transport to appointments)* • How easy was it to fit the best practice prevention part of the treatment into the family routine/daily life?

participants and their families		
Objectives	**Things to probe with participants**	**Things to probe with parents**
3. To explore the value and priority placed on the management of dental caries by participants and their parents	• When they first found out they had tooth decay how did they feel? How big a problem did they believe it to be? • After having treatment for the tooth decay what do they think about how big a problem tooth decay is? • How important do they think it is for their tooth decay to be treated? Why?	• When they first found out their child had tooth decay how did they feel? How big a problem did they believe it to be? • Now that they child has had treatment for the tooth decay what do they think about how big a problem tooth decay is? • How important do they think it is for children's tooth decay to be treated? Why?
4. To compare the experience and impact of the dental treatment upon the participants between the three treatment strategies		
5. To identify ways to improve the acceptability of the three treatment strategies for children and parents in future	• Can they think of any ways the treatment they received could have been better?	• Can they think of any ways the treatment their child received could have been better?

TOPIC GUIDE: DPs

Interview and Focus Group Topic Guide

Flexibility should be used when undertaking the interviews and applying the topic guide in terms of wording of questions, order of questions, use of probes/prompts and every opportunity made to allow participants to raise their own issues.

Opening:

- Write names on stickers
- Thank you for participating
- Purpose of focus group: Part of the National Institute for Health Research-funded FiCTION trial that your practice is taking part in. As you are aware, the aim of the FiCTION trial is to compare the clinical and cost-effectiveness of three treatment strategies for dental caries in children. In this part of the FiCTION trial we want to find out what you really think about these different strategies and how well they work (or not) in your dental practices.
- Few things to run through before we start
  - Confidentiality – information collected during the study is confidential and access will be restricted to our research team. When we analyse the data we won't use your real name but we will use the information you provide on the participant questionnaire (e.g. your job role). Some of your comments may be included in a report on the study or in articles for scientific journals but these will be completely anonymous. Please don't repeat what other people say outside of this session
  - No right or wrong answers
  - Everyone's views are of interest
  - Aim to hear as many different thoughts as possible
  - Likely to be different views, feel free to say what you think – OK to agree/disagree with others
  - Don't wait to be invited before stepping in, but don't talk over each other
  - Need to record so we can remember what is being said
  - Might make some notes while you're speaking – just to jog memory
  - Any questions?
  - Consent form

TURN ON AUDIO RECORDER

Introductions:

- Can you introduce yourself and tell us a bit about your background (e.g. age when qualified, years in practice, further qualifications, full-time/part-time, work in other clinical environments [hospital/teaching], children as a % of caseload) *(focus group moderator and note-taker begin)*

Perspectives on patient and parent/guardian preferences:

- What expectations do you think children have about how their dental caries will be managed?
- What expectations do you think parents/guardians have about how their children's dental caries will be managed?
- Do these expectations cause you to feel pressure to manage the children's dental caries in a particular way? Why/why not?
- Have you deviated from the allocated treatment arm for any patients because of this? If yes – why?
- How do patients respond to each of the three treatments?
- Which strategy do you think is most acceptable to them? Why?
- Which do you think is least acceptable? Why?
- How do parents/guardians respond when told what treatment their child would receive?
- Which strategy do you think is most acceptable to them? Why?
- Which do you think is least acceptable? Why?
- Why do you think some participants have dropped out?
- In your experience do any of the treatment strategies require more patient management than the others for adequate compliance?
- What do you think could be done to improve the acceptability of the management of dental caries for children?

  Probe: each specific strategy
- What do you think could be done to improve the acceptability of the management of dental caries for the parents/guardians of the children?

  Probe: each specific strategy

Previous experience:

As you know, the three treatment strategies we're comparing are conventional management + best practice prevention, biological management + best practice prevention and best practice prevention alone.

- What did you know about each of the three management strategies before taking part in the FiCTION trial?

- What training had you received in delivering the three management strategies before taking part in the trial?
- What experience did you have of delivering the three management strategies before taking part in the trial?
- What previous experience did you have of treating children?
- What previous experience did you have of managing children's behaviour?
- How have you found delivering the management strategies that you hadn't delivered before?

Experience of providing the three strategies in the trial:

- How was each of the management strategies carried out in your practice?
  Probe: what was delivered?, who delivered it, what did they do, how did they do it?
- How have you found following part 1 of the trial protocol: 'Participant allocation and treatment planning; which treatments for which study arm'? Why?
- How have you found following part 2 of the trial protocol: 'Supporting information for protocols; how to carry out designated treatments' for each of the three management strategies? Why?
  Probe: time to do so
- How do you find taking radiographs? Why?
- How do you find giving local anaesthetics? Why?
- Are you confident in your ability to deliver each of the three management strategies? Why/why not?
- Are you confident in delivering local anaesthetic? Why/why not?
- Are you confident in delivering pulp therapy for primary teeth? Why/why not?
- Are you confident in the long-term monitoring of teeth with Hall Technique crowns? Why/why not?
- Are you confident in your ability to carry out prevention that will arrest decay? Why/why not?
- Are you confident in your ability to carry out prevention that will lead to behaviour change in parents/guardians and children? Why/why not?
- Which management strategy is the most difficult to deliver? Why?
- Have you ever deviated from the protocol? If yes – what are the reasons for this?
- Do you have the resources you need to deliver each of the three management strategies? If no – what do you need that you don't have, e.g. equipment, time, staff?

- Thinking about the dental contract arrangements you work under, either the practice contracts or your own contracts, how do you feel about each of the three management strategies?
- Have there been changes in your practice, e.g. new owners (corporate bodies)?
- What are your views on whether each of these three management strategies benefits children's dental health?

  Probe: Do you believe that they achieve the goal equally well? Why/why not?
- What are your views on whether each of the three management strategies is what the dentist and/or other dental team members should be doing as part of their job role?
- Do you have any worries or concerns about managing the children's dental caries with any of the three management strategies? If yes – what are they?
- How well has your dental team as a whole adapted to the changes required to deliver the three strategies?

  Probe: using new materials, ICDAS caries coding, remuneration
- With a free choice, which of the three management strategies would you choose to deliver? Why?
- Would this differ between situations? What influences your decisions?

Future management of dental caries:

- How do you currently manage children who are not part of the FiCTION trial? Why?
- How will you manage children who have taken part in the trial once the trial is over? Why?
- How will you manage other children who have not taken part in the trial once the trial is over? Why?

If they would manage them in the same way that they did prior to participating in the trial:

- Why? What would have to change for you to manage them differently?

If they would manage them differently from how they would have prior to participating in the trial:

- Why? How will you implement the change?
- Does your dental practice/practice owner allow changes to be made to how you treat dental diseases as new technologies or evidence emerges?
- Do the General Dental Council (GDC), your defence society and your NHS Board allow changes to be made to how you treat dental diseases as new technologies or evidence emerges?

- Will the cost of resources for particular management strategies influence your decision about how to manage dental caries in children in the future? Why/why not?
- If the results of the FiCTION trial show that the outcome for best management requires a change in how you manage dental caries in children, what will you do?

If they would not implement the strategy for best management:

- Why not?

If they would implement the strategy for best management:

- How would you find making that change?

Probe: would habits, preferences, past experience make it difficult?

Translating the findings of research into clinical practice requires practitioners firstly to be aware of the findings, secondly to accept the findings and finally to adopt the findings into their practice.

- How can we best promote awareness of the findings of the trial among dentists and dental practice staff?
- How can we best encourage acceptance of the findings of the trial?
- How can we best encourage adoption of the treatment strategy that the trial finds to be the best way to manage dental caries in children?

Training needs:

- What are the skills required to deliver each of the three management strategies?
- Do you have all of these skills within your team? If no – what don't you have?
- How do you tell the patients and parents what you are going to do for each of the three management strategies?
- Were you taught communication strategies, in particular strategies for communicating with children, in your undergraduate or postgraduate training?
- How useful was the training for the FiCTION trial in equipping you to deliver the protocols for each of the management strategies?

  Probe: usefulness of clinical skills labs, lecture-based training, in-practice training
- Were you trained in how to communicate what you were going to do to the patients/parents?
- How well prepared did you feel for taking part in the trial following the training you were given?

  Probe: prepared for: administration, delivering the strategies, managing children's behaviour
- How do you think the training could be improved?

  Probe: type of training, materials, number and length of sessions, practice

Experience of being involved in research:

- What do you like about being part of the FiCTION trial? Why?
- What do you not like so much? Why not?
- Have you encountered any difficulties running the trial in your practice?
  Probe: problems with recruitment, consent, paperwork, outcome measurement (e.g. ICDAS), time to manage the trial commitment, radiographs
- What have you learned from being part of the FiCTION trial?
- How have you found the communication between the research team and the practice?
  Probe: how well does the research team communicate with you?, do you like the emails, face-to-face meetings, newsletters?, how well can you communicate with the research team?
- What is your experience of keeping participants in the trial?
- Why do you think some participants have dropped out?
- How do you think being involved in a trial has changed the patients' approaches to treatment?

You should have been sent some paperwork asking if your practice would be willing to take part in FiCTION Futures – future studies linked to the FiCTION trial. Participants recruited at practices that have expressed an interest in being involved in FiCTION Futures will be given the opportunity to consent to provide their contact details to the FiCTION team. Parents will be invited to read the information sheet at their child's routine appointment and provide consent/ complete the contact details form.

- Would you be willing to be involved in FiCTION Futures? Why/why not?
- Would you be willing to be involved in similar trials in the future? Why/why not?

End:

- Is there anything you would like to add, anything we've missed out?
- Is there anything else the note-taker would like to ask about?
- Thank you for participating – it's been very helpful and will help us to make recommendations to improve the future management of dental caries in children.