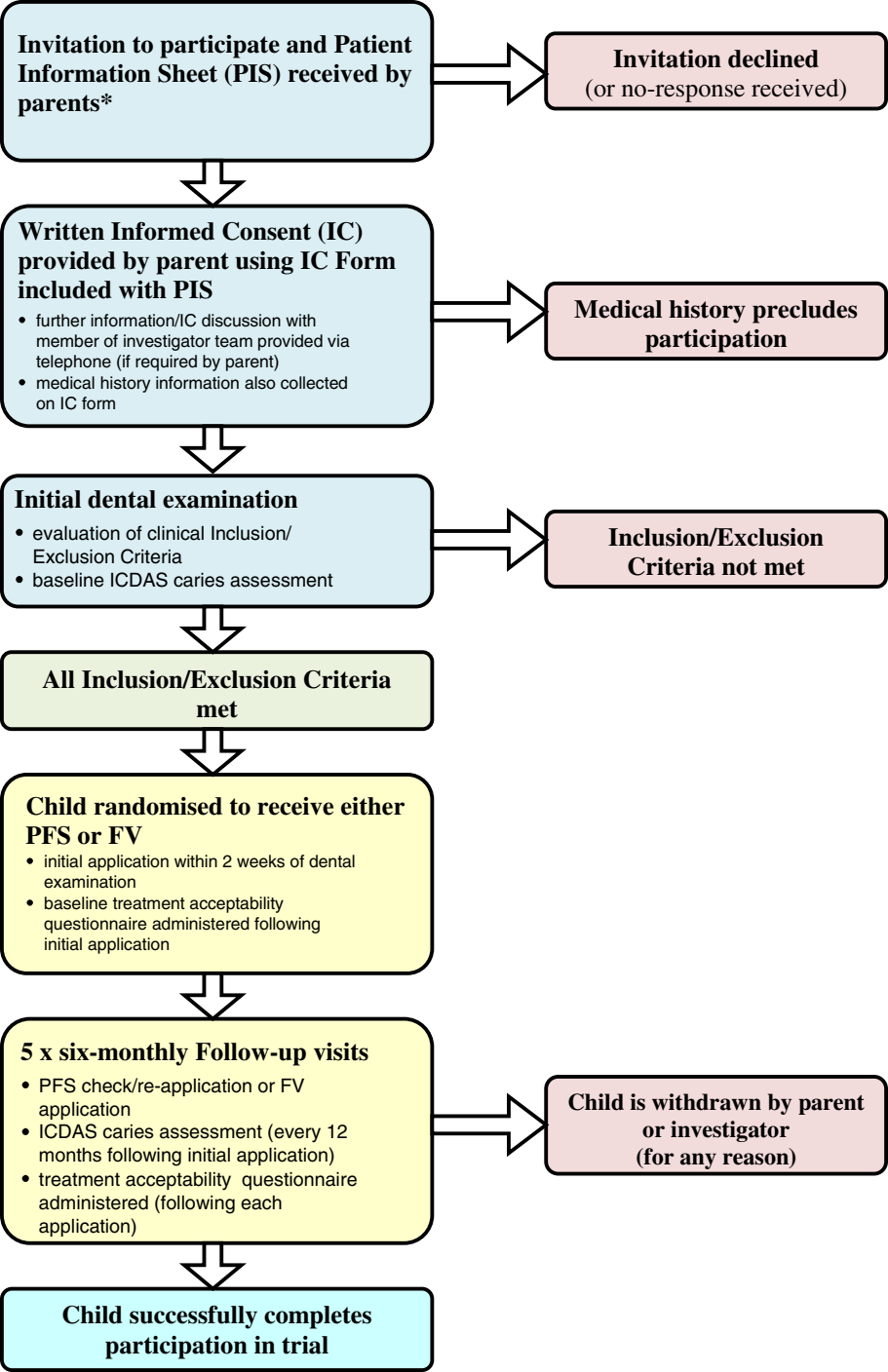
Invitation to participate and Patient Information Sheet (PIS) received by parents*
Invitation declined
(or no-response received)
Written Informed Consent (IC) provided by parent using IC Form included with PIS
• further information/IC discussion with member of investigator team provided via telephone (if required by parent)
• medical history information also collected on IC form
Medical history precludes participation
Initial dental examination
• evaluation of clinical Inclusion/ Exclusion Criteria
• baseline ICDAS caries assessment
Inclusion/Exclusion Criteria not met
All Inclusion/Exclusion Criteria met
Child randomised to receive either PFS or FV
• initial application within 2 weeks of dental examination
• baseline treatment acceptability questionnaire administered following initial application
5 x six-monthly Follow-up visits
• PFS check/re-application or FV application
• ICDAS caries assessment (every 12 months following initial application)
• treatment acceptability questionnaire administered (following each application)
Child is withdrawn by parent or investigator (for any reason)
Child successfully completes participation in trial