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| **Research Co-ordinator (1.0 EFT, PSP3), Yrs 1 – 5, Lead Site****Reason for Salary Request:**The Research Co-ordinator for this study will be a knowledgeable and self-directed researcher with significant multi-centre clinical research and management experience.**Responsibilities are in following areas:**1) Centrally co-ordinating the project to facilitate central ethics and local site specific approvals and ensure that all sites have met the appropriate regulatory requirements, TGA and contractual obligations. Managing ongoing reporting to ethics should amendments be required, or adverse events occur. 2) Organising and facilitating ongoing training and coordination of Site research staff from the point of study start up and onwards. This will include training in study recruitment, data collection and data entry into a secure web-based REDCap database.3) Coordination and liaison with other groups working with the study including the Database design consultant, Biostatistician, Health economist and the Data Safety Management Boards.4) Organising and reporting to the Study Steering Committee and the PREDICT Executive Committee. |
| **Research Assistant (0.8 EFT, PSP2) – Sites A,B,C,D,E,F,G,H, Yrs 2 - 4****Reason for Salary Request:** The Research assistant on-site will organise the study set up and initial and recurrent training of clinical emergency department staff about the study. They will facilitate recruitment and data collection for screened and recruited participants and entry of data into the centralised REDCap database using an IPAD. They will also report to local governance and the lead research team on recruitment progress at the site and help resolve local issues in consultation with the site PI.  |
| **Biostatistician (0.2 EFT, PSP 4), Yrs 1, 4 & 5Reason for Salary Request:** The biostatistician will provide expertise to the project for the design of the study and analysis of the data. They will be a self-directed researcher with significant research experience in paediatric clinical studies and the management of large data sets. They will commit 20% of their time in year 1, to set up data collection and the analysis plan, and 20% in years 4 and 5 to undertake data cleaning, analysis and reporting to the PI.  |
| **Health Economist (0.2 EFT, PSP 5), Yrs 1 & 5****Reason for Salary Request:**The health economist will oversee the health economic research undertaken in the proposed study. The health economist will be a senior, experienced researcher with significant relevant research experience in paediatric clinical studies. They will have input to the study design in use of appropriate health economic measures Year 1 and to the analysis and interpretation of findings Year. |
| **Implementation Scientist (0.2 EFT, PSP4), Yrs 5**An experienced implementation scientist is required at 0.2 EFT to undertake analysis of the barriers and enablers associated with changing practice in the emergency department setting, to develop targeted behaviour-change interventions. In year 5, qualitative interviews with site teams will be undertaken to gain understanding of clinical practice change at the site level. Data will be analysed and interpreted to ensure the results are optimised for implementability at the end of the trial. |
| **Administration Assistant (0.2 EFT, PSP 1), Yrs 1 – 5**Administrative support of 0.2 EFT per year is required at the lead site to assist the Co-ordinating Principal Investigator and the Research Co-ordinator with ordering and preparation of materials, co-ordination of meetings, organising freight, travel and training.  |
| **Consumer advisor honorariums, Yrs 1 – 5**Consumer advisors with lived experience of the research condition will be recruited to work with the research team to develop and design the study protocol, recruitment methods and participant materials. They will meet to review research progress throughout and be involved in the interpretation of study findings and appropriate messaging for the public. Five consumers will be recruited and paid an honorarium of $50 per hour for time spent. Year 1(n=5) = 4 x 2hr meetings, year 2 (n=5) - 4 = 2 x 1hr meetings, year 5 (n=5) = 2 x 2hr meetings. |
| **Data Base Consultant ($130ph)**A secure web-based database hosted on XXX server for this study will be designed and built by a database consultant. Certain aspects of the data set will be linked to electronic medical records at hospitals where available. Design and building costs will be incurred in the first year with maintenance funds required for subsequent years for updates, adjustments and specific reports. The consultant costs are charged at $130 per hour.Year 1 = 30hrs, Year 2 = 10hrs |
| **Clinical Trial Notifications ($360 per site)**This research project will be using study drugs in a research context. A Clinical Trial Notification (CTN) with the Therapeutic Goods Association in Australia will be required for each recruiting site at a cost of $360 per site for 8 Australian sites in year 1 of the study. |
| **Pharmacy costs ($500 per site x yrs 1 - 4)**Each site Pharmacy has administrative procedures associated with setting up the Clinical Drug Trial. This includes development of prescription, registering on iPharmacy, set up of trial folders, developing procedures for the trial. Following set up a yearly fee of $500 will be charged to cover administration procedures and completion of drug accountability and site closure documentation.  |
| **IPADs ($867 per site)**The Research assistants at each site will use IPADs to input data into REDCap for each patient as required. The IPAD provides flexibility for direct data input into the central RedCAP database from the Emergency Department and other locations. This contributes to improved data accuracy through data validation at input and reduction of transcription errors from hard copy case report forms.  |
| **Infographics, printing manuals, poster and training materials**To assist with providing families/caregivers from varied language backgrounds clear information about what participation in the study will involve, a short infographic will be produced to outline the study aims and procedures. Printing of study manuals, protocols and training materials, posters will be required for each site – particularly in year 1 and then to a lesser degree Years 2 - 4. Year 1 = $1600, years 2 – 4 = $500 |
| **Interview transcription costs, Yr 5**The research process evaluation will involve semi-structured interviews to be undertaken with 4 staff per site. Each interview recording will be approximately 1 hour long and transcription cost is $110 per hour. 8 sites x 4 staff =32 x $110 per hour.  |
| **Training - venue, catering and travel costs (n=20)**The ANZ Site based Research assistants and Site Principal Investigators will be required to attend a one day education and training meeting facilitated at the Royal Children’s Hospital / MCRI in year one (start-up). Catering/venue costs of $100 per head/day x 20 plus travel costs for a return flight and one night’s accommodation ($1000 per person) for 12 people have been costed (2 sites are local and will not incur travel costs). |
| **Travel for Site Visits (n=6 sites, 2 people)**The Lead Research Co-ordinator (Lead site) and Chief Principal Investigator will conduct yearly site visits (years 2 – 5) in order to review a selection of the site study data against source data, verify adherence to the protocol and confirm that research governance principles are being adhered to. Return flights and 1 night accommodation for travel interstate will be required at $1000 per person x 2 people X 6 sites (2 sites are local and will not incur travel costs). |
| **Participant incentive gifts ($20 per pt)**Child participants (n=approx. 600) will receive an age-appropriate gift to the value $20 upon recruitment. Funding for these payments is to ensure that children have a positive experience through their participation in the research.  |