**SCHEDA INFORMATIVA PER LA PARTECIPAZIONE AD UNA SPERIMENTAZIONE CLINICA**

**- MINORE DI ETA’ COMPRESA TRA 6 e 11 ANNI -**

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| **Indicare il titolo dello studio** |
| **Indicare la Struttura-contesto in cui si svolgerà lo studio** |

Caro/a ………………………………….,

i medici hanno chiesto ai tuoi genitori l’autorizzazione a farti partecipare ad uno studio clinico. Con questo documento vorremmo spiegarti in breve cos’è uno studio clinico ed in particolare in cosa consiste quello che viene proposto ai tuoi genitori. Saranno loro a decidere, ma è opportuno che tu sia informato. Ai tuoi genitori abbiamo fornito un documento simile a questo, solo molto più complesso.

Abbiamo pensato alle domande che probabilmente faresti tu, e abbiamo dato delle risposte che speriamo possano chiarire i tuoi dubbi. Naturalmente, potrai porre al medico che te ne parlerà tutte le altre domande che ti verranno in mente, in modo da avere le idee ben chiare in proposito.

Se, dopo aver esaminato il documento che è stato loro dato e aver avuto tutti i chiarimenti da parte del medico, i tuoi genitori decideranno che sia bene per te prendere parte allo studio, sarà loro richiesto di firmare un documento che si chiama “dichiarazione di consenso informato”.

A cosa serve questo studio clinico?

*[Adattare la descrizione a ciò che si intende sperimentare: Farmaco esistente? Nuovo farmaco? Nuova tecnologia?]*

Esempio per un nuovo farmaco:

Vorremmo valutare se può essere utile inserire nelle terapie anche il farmaco denominato XXXXXXX *(specificare nel dettaglio*). Gli studi condotti fino ad ora hanno dimostrato che tale farmaco funziona in modo sicuro anche nei bambini *(se applicabile).* Servono però altri studi per definire meglio come e a quali dosi funzioni nei bambini.

Dallo studio ci aspettiamo che:

*[Spiegare il razionale dello studio in termini semplici e sintetici identificando con chiarezza l’obiettivo dello studio]*

Immagine che contiene clipart

Descrizione generata automaticamenteEsempio per un nuovo farmaco:

il farmaco in sperimentazione aumenti le possibilità di guarigione (oppure: sia più efficace / sia più tollerato /abbia minori effetti collaterali/tardivi) di quelli attualmente in uso, ecc.

Che cosa mi accadrà durante lo studio?

*[Indicare il trattamento sperimentale e/o quello standard. Indicare gli esami e le visite previste]*

Esempio per un nuovo farmaco:

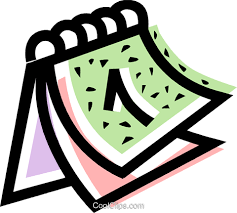
La partecipazione allo studio non è una cosa troppo diversa dalle cure che stai già ricevendo.

Prima di tutto ti faranno alcuni esami per verificare che tu possa davvero prendere parte allo studio.

Se così sarà, ti verrà prescritto un farmaco che dovrai assumere secondo le indicazioni del medico e sotto la guida dei tuoi genitori.

Ad intervalli regolari sarai sottoposto/a ad esami e visite di controllo durante le quali il dottore ti chiederà di dargli indicazioni su come ti senti.

Quanto durerà lo studio?

*[Indicare la durata dello studio]*

Lo studio che ti proponiamo durerà …………. mesi, durante i quali sarai tenuto/a in costante contatto con il centro dove viene sviluppato lo studio clinico.

Avrò qualche vantaggio dal partecipare allo studio?

*[Indicare i benefici attesi dalla partecipazione allo studio, anche con riferimento al progresso delle conoscenze scientifiche]*

Esempio per un nuovo farmaco:

I medici ipotizzano che questo trattamento sperimentale sia più utile contro la tua malattia rispetto ai trattamenti sin qui conosciuti, [in particolare per …. (specificare benefici?)], ma al momento ancora non ci sono prove di questo. Sappiamo però che le informazioni raccolte in questo studio aiuteranno i medici a saperne di più su questo nuovo trattamento e queste informazioni potrebbero aiutare i bambini in futuro affetti dalla tua stessa malattia.

Corro dei rischi nel partecipare allo studio?

*[Indicare i potenziali effetti avversi legati alla sperimentazione, ai farmaci e alle procedure che saranno utilizzate]*

**Tutte le pratiche mediche comportano dei rischi, anche quelle che già stai facendo.

In particolare, in questo caso ………… (specificare).

Sarai però sempre sotto controllo, come già sei adesso. Da parte tua, segnala subito ai tuoi genitori qualche fastidio che dovessi provare, come ad esempio mal di testa, mal di pancia, nausea, e i medici ti aiuteranno a stare meglio.

Mi spieghi meglio?

Immagine che contiene clipart

Descrizione generata automaticamente*[Sollecitare ulteriori domande da parte del minore]*

Puoi porre al medico tutte le domande che ti sembrano interessanti, e lui farà del suo meglio per darti risposte chiare e semplici.

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Speriamo che ciò che hai letto e sentito sia stato sufficiente a farti un’idea abbastanza chiara di cosa sia una sperimentazione clinica. A questo punto non resta che parlarne con i tuoi genitori.

![Immagine che contiene bambola, giocattolo

Descrizione generata automaticamente](data:image/jpeg;base64,/9j/4AAQSkZJRgABAQEAYABgAAD/4TFkRXhpZgAATU0AKgAAAAgABgALAAIAAAAmAAAIYgESAAMAAAABAAEAAAExAAIAAAAmAAAIiAEyAAIAAAAUAAAIrodpAAQAAAABAAAIwuocAAcAAAgMAAAAVgAAEUYc6gAAAAgAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAFdpbmRvd3MgUGhvdG8gRWRpdG9yIDEwLjAuMTAwMTEuMTYzODQAV2luZG93cyBQaG90byBFZGl0b3IgMTAuMC4xMDAxMS4xNjM4NAAyMDE5OjA5OjE1IDIyOjM4OjU5AAAGkAMAAgAAABQAABEckAQAAgAAABQAABEwkpEAAgAAAAMwMAAAkpIAAgAAAAMwMAAAoAEAAwAAAAEAAQAA6hwABwAACAwAAAkQAAAAABzqAAAACAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAA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