



Message from the staff Cell Biology Scientist

We are all glad that Spring is finally upon us, and temperatures are on the rise. After the long cold Winter we're happy to see the flowers bloom and the trees fill with green! Spring for me is a time of hope and renewal, and I enjoy this season perhaps most of all. It is only fitting we talk about the hope and chance at renewal that clinical trials bring to all of us. We've had many questions about clinical trials recently: What is a clinical trial? Who is eligible to participate? How can a child or loved one get enrolled? There are currently many clinical trials investigating the uses of cord blood and cord tissue. We'll touch upon these topics in this quarter's newsletter, just for you!

I also encourage you to take a look at our new website. It has many new features, and you can keep up with the newest and latest developments in the world of cord blood and cord tissue stem cells there! Check it out and tell us what you think!

-Matthew Wilgo, Cell Biology Scientist

Clinical Trials - A Primer

What is a clinical trial? Simply put it is an investigation on some form of treatment, that follows strict guidelines to ensure the new drug or procedure is safe and effective. While the process of clinical trials is both rigorous and robust, we'll try to simplify some of the basics for you, in a way that is easy to understand.

A clinical trial looks at some form of intervention. An intervention could be one of many different things such as a new drug, or a new surgical technique, or even a special type of diet. These interventions have often been studied in terms of research applications and may show promise in the laboratory, but often start with animal models, computer models, or cell based models. In order

Definitions:

Clinical Trial: A study designed to test the safety and efficacy of some form of intervention in human subjects.

Intervention: The treatment, drug, or procedure being investigated.

IRB: Internal review board.

to assess how well the intervention works in people it must be studied in human models.

A clinical trial is a multi-step process, broken down into what are called phases. Each phase has a specific purpose, and generally each successive phase adds more people to it, starting out small and ending large.

Phase 0 and 1 studies are small and have safety as the main goal, such as determining if there are any severe events, and how the drug is metabolized and excreted. Phase 2 studies are centered around determining the drug's effectiveness for a given condition. Participants are often compared with other test groups receiving a placebo (an inactive substance), or a standard treatment for the condition. Phase 3 expands the test population and further ascertains safety and effectiveness, often looking at different dosages and test populations. At this stage the FDA can approve or reject the intervention, but if approved, ongoing Phase 4 studies often take place to determine long term trends of the intervention.

Not everyone can participate in a clinical trial. Each trial is run by a principal investigator (PI), often a medical doctor, and a team of research-



ers such as doctors, nurses, and technicians; sometimes in multiple locations. There are very strict requirements specific to each clinical trial set forth in that trial's protocol. These requirements can be a great number of things such as age, gender and health. Often the study is approved and overseen by an Institutional review board (IRB), who determines if the benefits of the study outweigh the potential risks, and may monitor the study as it progresses.

Each patient signs and agrees to what is called informed consent. Informed consent goes over the scope of the study, details the expected risks and potential benefits. It is important to note this is not a binding contract, and that participants can withdraw from the study at any time for any reason.

Your primary care physician will be a great resource for what clinical trials are underway for specific medical conditions, and often will be critical into assisting you or your loved one to apply, if eligible.

While this is just a brief overview of the clinical trial process much more information can be found at www.ClinicalTrials.gov, and we encourage you to look for yourself there. Check our website for up to date information as well.

Check out one study on cord blood and cerebral palsy *A Randomized Study of Autologous Umbilical Cord Blood Reinfusion in Children with Cerebral Palsy*, at ClinicalTrials.gov - NCT01147653).

Getting to Know the New England Cord Blood Bank: Angela Dexter, Laboratory Manager.

Today we get to meet Angela Dexter, our esteemed manager at the blood bank. Angela is essential to the NECBB team and you'll be glad she's on the job. Angela's core duties include overseeing all the day to day operations of the blood bank, managing our cadre of industry lead-

ing technicians, and also ensuring each and every blood meets and is processed 100% to our rigorous quality standards.

Angela is also not afraid to get her hands dirty (figuratively speaking, we always have on our gloves and all processes are aseptic, aka 'sterile'!), and when a day turns out to be incredibly busy, she's right there assisting with the processing as well. Not all managers have that level of dedication, but Angela is a cut above the rest, and we love her for it!



When asked about her work, Angela says: "I love that our company is a family owned company. It often feels more like a family than work. It's always especially rewarding when a unit of cord blood goes out, and we receive word of a successful treatment. Knowing you helped saved someone's life isn't a reward of a regular job, and I find it very gratifying".

You can take comfort in knowing your cord blood was processed with skill and dedication!

Thank you for choosing NECBB to store your child's cord blood and tissue stem cells. Should you ever have any questions, please do not hesitate to contact us by phone, or email me directly at: DrGrace@necryogenic.com



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