

## Preface

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With great excitement, we present this inaugural edition of *Getting Started in Collecting for Biotherapies*. This project is a collaborative effort of apheresis physicians and allied health professionals across the United States, many of whom are considered experts in the field. As cellular therapy is expanding with numerous products at various stages of development, the demand for apheresis collection of mononuclear cells is growing exponentially.

Traditionally, many of these procedures were conducted at academic medical centers by their apheresis services. Currently, only a few such centers collect cells for biotherapies in the United States; most of which are located in large metropolitan areas. As more cellular therapy products become available and as more patients seek access to these therapies, many procedures should begin to be performed in community hospital settings or in more rural areas.

These developments present an opportunity for community hospitals and blood collection centers to start or expand their apheresis services to provide collections for local patients. As a facility evaluates this exciting opportunity to collect for biotherapies, many questions will likely arise on different topics, such as operations, finance, medical practice, legal logistics, quality, and regulatory issues. The main goal of this book is to familiarize readers with key essential information and provide answers to common questions that a facility may have when planning to expand its apheresis service or build a new facility to collect for biotherapies. Experienced apheresis collection facilities may also find the content helpful.

This resource is intended to assist facilities and health-care professionals at the beginning of a journey into apheresis collections

for biotherapies. It contains several key concepts on operations, finance, donor medical management, and apheresis technical aspects. A discussion of collecting cells from children is included because pediatric apheresis can be significantly different from procedures for adults. The discussion dedicated to vascular access is also crucial, given that this is a key factor in the success of cell collections. Cellular therapy is a highly regulated field and thus, quality program management and regulatory aspects are also briefly reviewed. Moreover, for those centers that would like to implement both collecting and processing for biotherapies, there is a companion publication to this book titled *Getting Started in Processing for Biotherapies* (AABB Press, 2024).

Many thanks go to the collaborative group of authors, the AABB Publications Committee, and AABB staff who have made this resource available expeditiously to the apheresis and cellular therapy community. Readers are encouraged to provide feedback(s) and to stay alert for additional new resources in development.

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