



StartSMART IBC Services

INTRODUCTION

The Sabai StartSMART IBC Services Program expedites Study Startup activities by preparing Sites that will be conducting Human Gene Therapy (HGT) research by proactively priming the site ahead of their inaugural Institutional Biosafety Committee (IBC) meeting and study initiation.

- Completion of the Sabai Institutional Agreement (document required to allow Sabai IBC to register site with NIH)
- Preparation of the NIH Registration process; to be completed once first study initiated
- IBC / Biosafety education so sites know what to expect and ask when preparing for a HGT study

TIER 1

- Work with the new Site to complete the Institutional Agreement ⇒ Startup timeline efficiency.
- Register the new site within the Sabai IBC portal.
- Registering the Site with the NIH is quicker once the IA is signed. Our team will create an IBC roster to include our IBC Chair, SMEs, local representatives and the site contact and get NIH roster approval in a 1-3 day period, once you have a study protocol and are ready to schedule your first IBC meeting.

TIER 2

- Sabai will provide IBC and Biosafety education to the Site to explain the NIH guidelines, what documents are required and what to expect from the IBC meeting.
- Biosafety professionals available to answer Site questions.
- Sites can prepare site documentation in advance and once selected for a HGT study can update necessary documents, saving time from Selection to IBC meeting and IBC approvals.

GETTING STARTED WITH

01

Schedule Call with Client Service team to set up Introduction Call

02

Complete the Institutional Agreement and Register in the IBC portal

03

Watch the IBC / Biosafety educational video [- 20 mins]

04

Site to begin to prepare documentation for first biosafety review