



# Investigator Resource Tool

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This Resource will assist you with:

- Learning Compass IRB's purpose
- Understanding Compass IRB's expectations
- References to some important regulations and guidances

## *A Message from the Board*

First let us say, thank you for choosing to work with Compass IRB.

As a Board, we've been charged with reviewing your study. The members of our Board took this responsibility very seriously. We pledge to you that we diligently apply all applicable federal regulations when we make our decisions. Additionally, we always follow the principals outlined in the Belmont Report, **RESPECT FOR PERSONS, BENEFICENCE and JUSTICE.**

We took special care and attention with the Informed Consent document for your study. We take personally the statement from the Nuremberg code that reads: *"The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity."* We took on this responsibility because we place the utmost importance on subject

safety and expect that you will do the same.

We promise we will never compromise when protecting human subjects; and expect you will never compromise either.

Strict adherence to Federal Regulations will be our starting point and we will always strive to exceed the expectations of an IRB.

If you ever have any questions regarding how to protect your subjects, how a regulation applies to you and your study, please always feel free to contact us.

## *Ongoing Commitments*

Because we promise to be continually committed to you, we ask the same of you and your research staff.

Now that you have been approved by Compass IRB, we would like to take a moment to let it be known that the investigator is obligated to adhere to all protocol re-

quirements and applicable federal requirements. All changes to the approved protocol must be reviewed before implementing (unless subject safety dictates immediate implementation).

At the time of submission, the investigator's responsibilities and obligations were

detailed on the last page of the application and agreed to by the Investigator's signature.

If at any time there are questions regarding an Investigator's responsibilities, please feel free to contact Compass IRB.

## Changes to Investigator's Information



### CHANGE OF ADDRESS

If there is a **change of address** during the course of your approval, Compass IRB should be notified promptly in order to update your information, as well as verify if there needs to be changes to your ICF.

### CHANGE TO THE 1572

When there is a change to Box #1 or #3 to the **FDA Form 1572**, the updated Form should be submitted to Compass IRB. For other changes, please consult your study Sponsor for reporting requirements.

### CHANGE OF PRINCIPAL INVESTIGATOR

If there is a **change of Principal Investigator (P.I.)** during the course of your approval, then the new P.I. must complete the Compass IRB Change of Principal Investigator Form as soon as a decision has been made to replace the existing Investigator.

## Safety Reporting to Compass IRB

Compass IRB expects the following unanticipated problems to be reported by Investigators/Sponsors/CROs:

- Adverse events which in the opinion of the principal investigator are both unexpected and related.
- An unanticipated event related to the research that exposes participants to potential risk
- An unanticipated event related to the research that exposes individuals other than the research participants (e.g., investigators, research assistants, students, the public, etc.) to potential risk
- Information that indicates a change to the risks or potential benefits of the research. For example: a) an interim analysis or safety monitoring report indicates that frequency or magnitude of harms or benefits may be different than initially presented to the IRB or b) a paper is published from another study that shows that the risks or potential benefits of your research may be different than initially presented to the IRB.
- A breach of confidentiality.
- Incarceration of a participant in a protocol not approved to enroll prisoners.
- Change to the protocol taken without prior IRB review to eliminate an apparent im-

mediate hazard to a research participant.

- Complaint of a participant when the complaint indicates unexpected risks or cannot be resolved by the research team.
- Protocol violation (meaning an accidental or unintentional change to the IRB approved protocol) that harmed participants or others or that indicates participants or others may be at increased risk of harm.
- Event that requires prompt reporting to the sponsor.
- Sponsor imposed suspension for risk.
- Any other event that indicates participant or others might be at risk of serious, unanticipated harms that are reasonably related to the research.

### **Protocol Deviations**

Compass IRB requires that *all significant deviations should be reported no later than ten (10) working days* from the day the Sponsor or Investigator becomes aware of the event. Compass IRB refers to deviations/violations from the approved study design collectively as Protocol Deviations. A protocol deviation is considered to be significant when the safety or confidentiality of the study subject or the scientific integrity of the study is compromised by any instance where the protocol was not followed.

“I believe that IRBs serve a very important function in protecting the subjects involved in clinical research and that ethics should be of the utmost importance.”

—Matt Baker, CIM CIP  
Compass IRB, LLC—President

## Advertising & Recruiting

All advertisements, recruitment and/or subject retention materials must be reviewed and approved by Compass IRB prior to use at your site.

The FDA Information Sheets state:

FDA expects IRBs to review the advertising to assure that it is not unduly coercive and does not promise a certainty of cure beyond what is outlined in the consent and the protocol.

In reviewing these materials, Compass IRB is going to determine if the advertisement is coercive.

Advertisements should not promise "free medical treatment," when the intent is only to say subjects will not be charged for taking part in the investigation.

Advertisements may state that subjects will be paid, but should not emphasize the payment or the amount

to be paid, by such means as larger or bold type.

In the event that a television or radio advertisement is being created for recruitment use, Compass IRB strongly recommends submitting the script for approval prior to the final recording of the actual commercial.

Compass IRB requests copies of final run ads.



## Pediatric Research Studies

Compass IRB regularly reviews pediatric studies in accordance with 21 CFR 50 and 45 CFR 46; Subpart D.

The Board will classify each pediatric study into one of 4 categories.

1. (50.51 & 46.401) *Clinical investigations not involving greater than minimal risk.*

2. (50.52 & 46.402) *Clinical investigations involving greater than minimal risk but presenting the prospect of direct benefit to individual subjects.*

3. (50.53 & 46.403) *Clinical investigations involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowl-*

*edge about the subjects' disorder or condition.*

4. (50.54 & 46.404) *Clinical investigations not otherwise approvable that present an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.*

The Board's decision will be noted on your approval letter.

## Medical Device Studies

Compass IRB regularly reviews medical devices.

Per 21 CFR 812, the Board will determine if the study is Non-Significant Risk (NSR) or Significant Risk (SR). This determination will be listed on your approval letter.

Compass IRB requires that all **serious and unanticipated** adverse device effects must be

reported within 10 days of your notification of the event.

21 CFR 812.3(s):

*Unanticipated adverse device effect* means any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified

in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

For more information on Medical Devices, we recommend visiting:  
<http://www.fda.gov/oc/ohrt/irbs/default.htm>

## *Reminder of Principal Investigator's Responsibilities*

As part of our commitment to you and your study staff, we would like to remind you that as a Principal Investigator it is your responsibility to ensure that:

- You and your research staff use recruitment processes that are fair and equitable
- Although a subject is not obliged to give his or her reason for withdrawing prematurely from the clinical trial, the investigator should make a reasonable effort to ascertain the reason, while fully respecting the subject's rights
- When conducting the research study, you, the investigator, have the resources necessary to protect your human participants including sufficient time to conduct and complete the research, as well as, access to a population that will allow recruitment of the necessary number of subjects.
- You and your research staff do not use exculpatory language when communicating with a prospective subject or the legally authorized representative
- You will provide evidence of such qualifications through up-to-date curriculum vitae or other relevant documentation requested by the sponsor, the IRB, or the regulatory authority
- That you are familiar with the appropriate use of the investigational product(s), as described in the protocol, in the current investigator's brochure, in the product information and in other information sources provided by the Sponsor
- You notify the IRB should the Sponsor terminate or suspend the research
- You will promptly notify the Sponsor should the IRB terminate or suspend its approval of the research
- You will provide written reports to the IRB should any changes significantly affect the conduct of the clinical trial or increase the risks to subjects
- You will maintain a list of appropriately qualified persons to whom you, the Investigator, has delegated significant trial-related duties
- You will report all Serious Adverse Events (SAEs) to the Sponsor except for those SAEs that the protocol or other documents detail as not needing immediate reporting
- You will follow all regulatory requirements related to the reporting of unexpected serious adverse drug reactions to the regulatory authority and Compass IRB
- For reports of deaths, the investigator supplies the IRB with any additional requested information (e.g. autopsy reports and terminal medical reports)



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### ***Authority of Establishment***

*Compass Independent Review Board, LLC operates in accordance with FDA 21 CFR and 45 CFR and ICH guidelines.*