

DF/HCC ONCORE GUIDANCE

Registration Safety Mechanisms and Exceptions

OnCore has controls in place to prevent co-enrollment to more than one therapeutic protocol, and to prevent duplicate registrations. In exceptional cases, these controls may need to be overridden.

Ultimately, the investigators and study teams are responsible for ensuring the safety of clinical trial subjects, all applicable DF/HCC and institutional policies are followed, and appropriate approvals (e.g., sponsor, PI, treating physician, etc.) are in place. ODQ will only facilitate the registration process and a subject's association to a protocol in OnCore. ODQ will not assess the clinical and/or safety implications of overriding these controls, or verify subject eligibility for co-enrollment or re-enrollment.

I. Registration to Multiple Therapeutic Protocols

OnCore prevents a subject from being associated with more than one protocol that has the 'Involves Therapy' field set to 'Yes'. ODQ is responsible for setting the 'Involves Therapy' field.

The following steps must occur in order to concurrently enroll a subject in two therapeutic protocols, or a therapeutic protocol and a BMT Treatment Plan:

1. The Overall PIs of both protocols/treatment plans must agree to concurrently enroll the subject and provide written approval to ODQ. Email is acceptable.
 - a. In some cases, the Overall PIs may provide blanket approval to concurrently enroll future subjects to a specific combination of protocols/treatment plans. In this case, ODQ will enter a notation in the applicable protocol records.
2. Upon receipt of the required approvals, ODQ will perform a temporary toggling of the 'Involves Therapy' field in order to allow co-enrollment. ODQ will return the 'Involves Therapy' field to 'Yes' to ensure this safety mechanism is in place for future enrollments.

II. Re-registration of a Subject to a Protocol

By default, OnCore will not allow duplicate registration of a subject to the same protocol. ODQ is responsible for setting the 'Allow Duplicate Enrollment?' field.

The following steps must occur in order to re-enroll a subject to a protocol:

1. Sponsor approval is required in order to re-enroll a subject to a protocol. Written approval from the Overall PI and Sponsor must be provided to ODQ. Email is acceptable.
2. Upon receipt of the required approvals, ODQ will toggle the 'Allow Duplicate Enrollment?' field.