**YALE UNIVERSITY**

**INSTITUTIONAL REVIEW BOARDS**

**Prospective Single Subject Protocol Modification/Deviation**

**700FR2**

**FOR ONE-TIME REQUEST ONLY**

Please review the short presentation on this topic, which can be found at http://www.yale.edu/hrpp/

Please use this form for one subject.

If there is an intention to use this form for more than one subject, please submit an amendment request instead. Do **not** use this form for routine, non-significant reporting of issues such as out-of-window or rescheduled visits**.**

***If the investigator is also the sponsor, this form may not be used. An amendment must be submitted.***

Please note that an investigator must receive Board approval **before** initiating any change to the research ***unless*** t*he change is intended to eliminate an apparent immediate hazard to subjects, in which case it may be implemented immediately provided the IRB is subsequently notified in accordance with 21 CFR 56.104(c). In this case, the change should be reported to the HIC.*

|  |  |
| --- | --- |
| Date Needed By:  |       |
| PI Name: |       |
| Study Title:  |       |
| HIC Protocol #: |       |
| Name of Correspondent: |       |
| Phone:  |       | E-mail:  |        |
| Participant ID or Study Number: |       |

1. Has the sponsor (or designee) approved this protocol waiver/exception request?

[ ]  Yes. (Please attach a copy of sponsor (or designee) approval of the waiver/exception.

[ ]  No. Sponsor (or designee) approval must be provided at the time of this submission.

1. Has this same protocol waiver/exception request been submitted on any other occasion for this protocol/study?

[ ]  Yes [ ]  No

1. Do you think this protocol waiver/exception request may be requested again?

[ ]  Yes [ ]  No

1. Type of Request

[ ]  Inclusion/Exclusion Criteria deviation

[ ]  Request for subject to remain in study despite reaching an endpoint or progression of disease

[ ]  Request for dosing variance

[ ]  Other

1. Description of the request (what will be done differently for this participant)

1. Rationale for the request (why this request is necessary)

1. Check all that apply (if any of these items are checked, please provide an explanation)

[ ]  The request will result in increased risk to this subject

[ ]  The request will affect the rights, safety or welfare of other participants

[ ]  The request will affect the integrity of the data for the study

[ ]  None of the above

[ ]  Other or explanation of above items

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **Principal Investigator’s Signature** |  | **Date** |

Note: Please provide complete and comprehensive answers to the questions. The HIC will make every effort to review this form by the requested date. If possible, the approval will be obtained from the Chair via expedited review. **If the request does not meet the criteria for expedited review, it will be sent to Full Board.**