Treatment Protocol Checklist

(Compassionate Use/Expanded Access/Treatment IND)

[ ]  Full Board Review [ ]  Initial Review

[ ]  Expedited Review [ ]  Continuing Review

Reviewer:       Submission ID:

Principal Clinician:       Protocol #:

Do you have a conflict of interest with this protocol? Yes [ ]  No [ ]

Are you reviewing an IND or IDE protocol? IND [ ]  IDE [ ]

For expedited reviews, all sections must be completed for documentation purposes.

[ ]  Check here if the checklist is completed for review of an amendment. Complete only the sections that are affected by the amendment.

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| **SUMMARY OF FINDINGS AND RECOMMENDATIONS** |
|  | **YES** | **NO** | **Comments or N/A** |
| 1. **Sites**
2. Indicate affiliated sites using drug or device:

**[ ]**  UCD-AMC**[ ]**  University Hospital (including CTRC) **[ ]**  CHCO (Main) **[ ]**  CHCO (Satellite):      **[ ]**  Denver Health (DHHA approval received/in place **[ ]** )1. Has UCD HSR Portal Clearance been received?
2. Indicate VA involvement:

**[ ]**  Non-VA protocol**OR****[ ]**  VA-only**[ ]**  Multi-site protocol involving VA  (Confirm VA Purple Clearance Letter has been received **[ ]** )1. **IDE protocol** - Device Control and Storage: If the protocol involves multiple affiliated sites, are there separate plans for order and storage of devices at each site? (Attachment D?)
2. **IND protocol** - Drug Handling and Control: If the protocol involves multiple affiliated sites, are there separate plans for secure reception and storage of the drug at each site?
 | [ ] [ ] [ ]  | **[ ]** **[ ]** **[ ]**  |      **[ ]**  N/A**[ ]**  N/A     **[ ]**  N/A      |
| 1. **IND/IDE Information**
2. What is the IND/IDE number?
3. Who holds the IND/IDE?
4. Who is providing the drug/device?
 |  |  |       |
| 1. **Consent/Advisory Form**
2. Does the Patient Advisory form/consent form adequately inform patients of the following?
3. Procedures
4. Risks
5. The drug/device is not FDA approved
6. Alternative treatment
7. For children,
8. Is parental permission sought?
9. Is the permission of one parent sufficient?
10. Are there any circumstances where consent will not be obtained prior to use of the drug/device?
11. ► If yes, is this acceptable?
12. Are any additional protections needed in this case?
13. ► If yes, what kind of protections needs to be in place?

     1. If changes are made to the consent/advisory form, do the changes require re-consenting patient? Why/why not?

      | [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]  | [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]  |      [ ]  N/A[ ]  N/A          [ ]  N/A |
| 1. **Risk/Benefit**
2. Is there prospect of direct benefit to the patients?
3. For what condition patients will receive treatment?

      | [ ] [ ]  | [ ] [ ]  |       |
| 1. **Continuing Review Cycle**
2. Is the 12-month review period adequate?
3. ► If no, why not?
4. What is the appropriate review period?       months [ ]  N/A
5. Rationale for the 12-month review period:

 [ ]  Specific experience of the providers [ ]  Anticipated low patient inclusion due to patient population [ ]  Risks and adverse events are expected to be low [ ]  Structured stopping criteria [ ]  Close monitoring of patients [ ]  Appropriate safety monitoring plan | [ ]  | [ ]  |       |

Reviewer Addendum for Continuing Review:

N/A [ ]  (check N/A if this is an initial review or amendment)

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| **SUMMARY OF FINDINGS AND RECOMMENDATIONS** |
|  | **YES** | **NO** | **Comment or N/A** |
| 1. Is the number of patients accrued consistent with the IRB approved number?
 | [ ]  | [ ]  |       |
| 1. Do the patient withdrawals indicate a problem with the protocol that needs correction?
 | [ ]  | [ ]  |       |
| 1. Have all previously approved amendments been appropriately incorporated into the appropriate documents?
 | [ ]  | [ ]  |       |
| 1. Is the current consent/advisory form accurate and complete?
 | [ ]  | [ ]  |       |
| 1. Have any unforeseen problems or accidents occurred?

 ► If yes, has the IRB been properly informed? | [ ] [ ]  | [ ] [ ]  |      [ ]  N/A |
| 1. Have any adverse events that warrant changes to the protocol and/or consent/patient advisory form?
 | [ ]  | [ ]  |       |
| 1. Since the last IRB review, is there new information that might require changes to the protocol and consent/patient advisory form?
 | [ ]  | [ ]  |       |
| 1. Do the potential benefits of the protocol continue to outweigh the known risks?
 | [ ]  | [ ]  |       |

Amendment Review:

N/A [ ]  (check N/A if this is an initial or continuing review only)

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| **OVERVIEW OF CHANGES** |
|  | **YES** | **NO** | **Comment** |
| 1. Is the change clearly reflected in the revised documents submitted?
 | [ ]  | [ ]  |       |
| 1. Does this change affect the purpose of the protocol from treatment to research?
 | [ ]  | [ ]  |       |

**Additional Comments:** [ ]  N/A

Sign Here

**Reviewer Date**