NCI Clinical Trials Terms of Award Checklist

This checklist serves as a reminder of information that must be maintained by the awardee and submitted to NCI when requested.

1. Requirements at Time of Competitive Application/Proposal

- ❑ The research plan, including protocol, if required by the Funding Opportunity Announcement
- ❑ Data and safety monitoring plan (DSMP)
- ❑ Targeted/Planned Enrollment Table

2. Requirements Prior to Patient Enrollment

- ❑ IRB or IEC documents and protocol or protocols, identified by version number, date, or both; maintain the following for each investigative site or IRB and provide if requested by NCI.
    - IRB or IEC name.
    - Federal-wide assurance number for institution or site.
    - IRB or IEC notification of protocol approval.
    - IRB or IEC approved protocol.
    - IRB or IEC approved consent forms identified by dates valid.

- ❑ DSMB proposed roster and CVs: submit to NCI for approval

- ❑ ISM, SMC, or DSMB information, maintain and provide if requested by NCI (may include charter, operating procedures, and other elements of DSMP tailored to trial)

- ❑ Additional information for clinical trials with INDs or IDEs. Maintain and provide if requested by NCI
    - Name, institution, and address of IND or IDE sponsor.
    - FDA IND or IDE number.
    - FDA correspondence
    - Risk information (e.g., investigator's brochure, or information obtained through published literature review or other venue).

- ❑ Additional information for gene transfer clinical trials. Maintain and provide if requested by NCI
    - NIH Recombinant DNA Advisory Committee (RAC) initial review.
        - Date of letter from Office of Biotechnology Activities (OBA): _____ NA_____
        - Selected for Public RAC Review: Yes____ No: ____
        - Letter from the Office of Biotechnology Activities either:

            1) Stating the protocol has been exempted from public review, or

2) Summarizing the RAC's suggestions

- PI's response to RAC recommendations (if applicable)
- Institutional Biosafety Committee (IBC)-related documents for human gene transfer protocols.
  - Name of institution IBC serves.
  - Copy of written IBC approval of protocol.
  - Copy of protocol approved by the IBC and IRB.

❑ Documentation of training in human subjects protection for all study staff responsible for design or conduct of the research.

3. Ongoing Reporting Requirements Following Patient Enrollment

☐ Documentation of IRB or IEC continuing reviews – maintain the following for each investigative site, and provide to NCI if requested:

- OHRP federal-wide assurance number for site.
- IRB or IEC approved consent form identified by version number, date, or both and dates it is valid.
- IRB or IEC approved protocol identified by version number, date, or both unless otherwise directed.

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☐ Changes in IRB or IEC approval status -- submit to NCI by email or fax within three working days of IRB or IEC decision.

- Unplanned termination or unplanned temporary suspension of patient accrual.
- Unplanned termination or temporary suspension of the protocol.
- Any other change in IRB or IEC approval status.
- Any other problems or issues that could adversely affect the participants in the study.
- Letter from Principal Investigator and Business Official detailing the change of IRB or IEC approval and copies of any IRB or IEC responses.

☐ Protocol amendments or documents related to an amended protocol – if requested, submit to the NCI prior to implementing changes.

☐ Data and safety monitoring reviews or summaries, if requested by NCI.

☐ Changes in IND or IDE status – notify the NCI program or project officer in writing if the FDA or other regulatory authority places the study on clinical hold at any time.

☐ For studies where NCI holds the IND, report adverse events to NCI monitoring staff according to instructions in the protocol.

☐ For studies where NCI does not hold the IND, report adverse events to FDA according to FDA procedures.

☐ Documentation for Gene Transfer Clinical Trials

- Submit safety reports to OBA and local IBC, and provide if requested by NCI
- Document IBC continuing approval, and provide if requested by NCI

☐ Training in human subjects protection for new study staff **–** submit annually to coincide with each noncompeting renewal or annual progress report.

☐ Inclusion enrollment reports **–** submit annually to coincide with each noncompeting renewal or annual progress report.