

CELL LINE AUTHENTICATION POLICY

PURPOSE

The contamination or misidentification of cell cultures can seriously compromise research performed with such Cell Lines. The purpose of this policy is to ensure that information generated using cultured cells at The University of MD Anderson Cancer Center (MD Anderson) is obtained from samples that have been authenticated by DNA Validation techniques, to rule out misidentification and inter- or intra-species contamination. This will prevent the necessity for retraction of papers in which Cell Lines are found not to be of the reported lineage. It has been indicated by NIH that grant applications that fail to use acceptable experimental practices “would not fare well in the review process.”

POLICY STATEMENT

Validation by DNA analysis will be performed on Cell Lines used to produce scientific information at MD Anderson. This Validation process will enhance the quality of research at MD Anderson and maintain the scientific integrity and reputation of the institution.

SCOPE

Compliance with this policy is the responsibility of all faculty, trainees/students, and other members of MD Anderson’s workforce.

TARGET AUDIENCE

The target audience for this policy includes, but is not limited to, all faculty, trainees/students, and other members of MD Anderson’s workforce utilizing Cell Lines for research.

DEFINITIONS

Cell Line: Line established by sub-culturing a primary culture of cells from a human or animal following immortalization.

STR Profiling: Short Tandem Repeat analysis of DNA.

Validation: Identification of origin of cells through DNA analysis techniques.

PROCEDURE

1.0 Validation of Cell Lines

- 1.1 Annual Validation of actively used Cell Lines is required by a variety of methods, one of which could be STR Profiling. This is available through the institutional CCSG Characterized Cell Line Core.
- 1.2 Cell Lines that have been put through a biologic selection process (*e.g.*, selection for drug resistance, passage through animals, cell cloning) require fingerprinting to validate origin.
- 1.3 Validation of origin of Cell Lines received from other institutions or MD Anderson labs is necessary unless the internal lines were received from the CCSG core validated seed stocks or a reputable Cell Line repository such as the American Type Culture Collection.
- 1.4 Validation of origin of all newly established human Cell Lines is required.
- 1.5 Cell Lines that are being transported to a recipient outside of this institution will be required to be shipped with the fingerprinting validation provided to the recipient.
- 1.6 Validation is to be performed on Cell Lines that have been inactive (*i.e.*, frozen) when reactivated unless these are seed stocks that were verified prior to freezing the stock culture.
- 1.7 Other validations can be added by the researcher to protect the integrity of his/her research.
- 1.8 The Validation results of the Cell Lines used to generate a paper submission or a grant proposal will be necessary after grant approval or paper acceptance (Just in Time (JIT)).
- 1.9 This policy is intended to be a baseline for reporting Cell Line Validation results. Researchers should ascertain the reporting requirements for the individual funding and publishing groups.

2.0 Training

- 2.1 All new faculty and their lab personnel who utilize Cell Lines will be required to review the training information regarding Cell Line Validation.
- 2.2 All faculty and their personnel who utilize Cell Lines will review the training information every four (4) years.

3.0 Compliance

- 3.1 In order to protect the reputation and standing of the institution, ensure its continued eligibility for federal and state funding, and preserve the integrity of affiliated research, disciplinary action may be warranted for noncompliant individuals subject to this policy.
- 3.2 In the event of noncompliance with this policy, the Provost or designee shall communicate a directive in writing to the noncompliant faculty member for the elimination of such noncompliance.
- 3.3 If a faculty member does not comply with a directive of the Provost, the following disciplinary actions may be imposed upon the noncompliant individual, at the discretion of the Provost: (1) grant funding will not be released until Validation of pertinent Cell Lines (JIT); (2) the individual may be ineligible for internal funding; and (3) certifications for grant submissions may be held. Any or all of the above may negatively impact the individual's research endeavors.

ATTACHMENTS / LINKS

None.

RELATED POLICIES

None.

JOINT COMMISSION STANDARDS / NATIONAL PATIENT SAFETY GOALS

None.

OTHER RELATED ACCREDITATION / REGULATORY STANDARDS

None.

REFERENCES

British Journal of Cancer, "UKCCCR Guidelines for the Use of Cell Lines in Cancer Research," 82, no. 9 (2000): 1495-1509. <http://www.nature.com/bjc/journal/v82/n9/pdf/6691169a.pdf>

National Institutes of Health (NIH), *Notice Regarding Authentication of Cultured Cell Lines*, November 28, 2007. NOT-OD-08-017, <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-017.html>

POLICY APPROVAL

Approved With Revisions Date: 10/25/2013

Approved Without Revisions Date:

Implementation Date: 10/25/2013

Version: 11.0

RESPONSIBLE DEPARTMENT(S)

Office of Research Administration & Operations