Vericel Adverse Event (AE) Report Form

Report Event(s) to PatientSafety@vcel.com within 1 Business Day of Receipt

*Required fields

*Your Name: *Today's Date:

*Date you learned of this Event: *Date of Treatment:

*Product(s): (select all that apply) ☐ MACI ☐ Epicel ☐ Carticel ☐ MACI Biopsy Kit ☐ Epicel Biopsy Kit ☐ Surgical Instruments ☐ Other:

Lot Number(s):

PATIENT IDENTIFIERS (*check at least one)

Sex: ☐ Male ☐ Female DOB: Age:

Description of Patient: ☐ Fetus ☐ Neonate ☐ Infant ☐ Child ☐ Adult ☐ Elderly

EVENTS (*check one)

☐ Adverse Event ☐ Off Label Use (anything other than approved indication) ☐ Product Complaint ☐ Other (ex. Pregnancy/ Lactation Exposure)

REPORTED TERM(S) & BRIEF DESCRIPTION

AEs ONLY

Start Date of AE:

Outcome: ☐ Ongoing ☐ Resolving ☐ Recovered, if so when:

Check all that apply:

☐ Death, if so, date of death: Cause of death:

☐ Hospitalization (initial or prolonged), if so, dates of hospitalization:

☐ Life-threatening ☐ Congenital Anomoly/ Birth Defect ☐ Disability or Permanent Damage ☐ Other Series (Important Medical Event)

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CAUSALITY AEs ONLY

Does the reporter believe that the Event is related to the Vericel Product?

☐ Definitely related ☐ Probably related ☐ Possibly related ☐ Unlikely related** ☐ Not related**

**If Unlikely Related or Not Related, what is most likely the cause, per the reporter?

EMPLOYEE NAME & CONTACT INFO

*Name:

*Phone Number:

*Email Address:

*Title:

INITIAL REPORTER (person who initially reported the event to you)

*Name:

*Phone Number

*Email Address:

*Address:

*Credentials: