What is claimed is:

1. Use of replication incompetent recombinant retroviral particles in the manufacture of a kit for administering a cell formulation to a subject, wherein the use of the kit comprises:

a) contacting blood cells comprising the T cells and/or NK cells *ex vivo* in a reaction mixture comprising a T cell and/or NK cell activation element, with the replication incompetent recombinant retroviral particles, wherein the replication incompetent recombinant retroviral particles comprise:

i) a binding polypeptide and a fusogenic polypeptide on the surface of the replication incompetent recombinant retroviral particles, wherein the binding polypeptide is capable of binding to a T cell and/or NK cell, and wherein the fusogenic polypeptide is capable of mediating fusion of a retroviral particle membrane with a T cell and/or an NK cell membrane; and

ii) a polynucleotide comprising one or more transcriptional units, wherein each of the one or more transcriptional units is operatively linked to a promoter active in T cells and/or NK cells, wherein the one or more transcriptional units encode a first polypeptide comprising a chimeric antigen receptor (CAR),

wherein said contacting facilitates association of the T cells and/or NK cells with the replication incompetent recombinant retroviral particles, and wherein the replication incompetent recombinant retroviral particles modify the T cells and/or NK cells; and

b) administering the cell formulation to the subject subcutaneously, wherein the cell formulation comprises the modified T cells and/or NK cells, and wherein:

i) the reaction mixture comprises at least 25% unfractionated whole blood by volume,

ii) the reaction mixture comprises neutrophils, and/or

iii) the modified T cells and/or NK cells are administered subcutaneously in a delivery solution along with neutrophils.

2. A cell formulation, comprising modified T cells and/or NK cells, wherein the modified T cells and/or NK cells are suspended in a delivery solution and are either or both,

a) genetically modified with a polynucleotide comprising one or more transcriptional units, wherein each of the one or more transcriptional units is operatively linked to a promoter active in T cells and/or NK cells, or

b) associated with a replication incompetent recombinant retroviral particle comprising the polynucleotide,

wherein the one or more transcriptional units encode a first polypeptide comprising a chimeric antigen receptor (CAR), wherein the cell formulation has a volume of between 2 ml and 10 ml and further comprises neutrophils, and wherein the cell formulation is contained within a syringe.

3. Use of a replication incompetent recombinant retroviral particles in the manufacture of a kit for administering modified T cells and/or NK cells to a subject, wherein the use of the kit comprises: administering a cell formulation comprising the modified T cells and/or NK cells to the subject subcutaneously, wherein the modified T cells and/or NK cells are either or both, a) genetically modified with a polynucleotide comprising one or more transcriptional units, wherein each of the one or more transcriptional units is operatively linked to a promoter active in T cells and/or NK cells, or b) associated with a replication incompetent recombinant retroviral particle comprising the polynucleotide, wherein the one or more transcriptional units encode a first polypeptide comprising a chimeric antigen receptor (CAR), and wherein at least one of neutrophils, B cells, monocytes, basophils, and eosinophils are administered subcutaneously in the cell formulation along with the modified T cells and/or NK cells.

4. A method for preparing a cell formulation, comprising

a) contacting blood cells comprising the T cells and/or NK cells *ex vivo* in a reaction mixture comprising a T cell and/or NK cell activation element, with replication incompetent recombinant retroviral particles, wherein the replication incompetent recombinant retroviral particles comprise:

i) a binding polypeptide and a fusogenic polypeptide on the surface of the replication incompetent recombinant retroviral particles, wherein the binding polypeptide is capable of binding to a T cell and/or NK cell, and wherein the fusogenic polypeptide is capable of mediating fusion of a retroviral particle membrane with a T cell and/or an NK cell membrane; and

ii) a polynucleotide comprising one or more transcriptional units, wherein each of the one or more transcriptional units is operatively linked to a promoter active in T cells and/or NK cells, wherein the one or more transcriptional units encode a first polypeptide comprising a chimeric antigen receptor (CAR),

wherein said contacting facilitates association of the T cells and/or NK cells with the replication incompetent recombinant retroviral particles, wherein the replication incompetent recombinant retroviral particles modify the T cells and/or NK cells, and wherein the reaction mixture comprises neutrophils;

b) collecting the modified T cells and/or NK cells in a delivery solution to form a cell formulation comprising a suspension of the modified T cells and/or NK cells; and

c) transferring 0.5 ml to 10 ml of the cell formulation into a syringe.

5. Use of a population of modified T cells and/or NK cells in the manufacture of a kit for subcutaneous or intramuscular delivery to a subject, wherein the use of the kit comprises, delivering between 0.2 and 10

ml of a cell formulation comprising the modified T cells and/or NK cells to the subject subcutaneously, wherein the modified T cells and/or NK cells are genetically modified with a polynucleotide comprising one or more transcriptional units, wherein each of the one or more transcriptional units is operatively linked to a promoter active in T cells and/or NK cells, and wherein the one or more transcriptional units encodes a first polypeptide comprising a chimeric antigen receptor (CAR) and a second polypeptide comprising a lymphoproliferative element that comprises an intracellular signaling domain from a cytokine receptor.

6. A use, method, or cell formulation according to any one of claims 1 to 5, wherein the one or more transcriptional units encode a second polypeptide comprising a lymphoproliferative element that comprises an intracellular signaling domain from a cytokine receptor, optionally that activates a Janus kinase/ Signal Transducer and Activator of Transcription (JAK/ STAT) pathway or a tumor necrosis factor receptor (TNF-R)-associated factor (TRAF) pathway.

7. A use or method according to claim 6, wherein the lymphoproliferative element is constitutively active and comprises Box 1 and Box2 JAK-binding motifs and a STAT-binding motif comprising a tyrosine residue.

8. A use or method according to claim 6, wherein the lymphoproliferative element does not comprise an extracellular ligand-binding domain or a small molecule binding domain

9. A use according to any one of claims 1 or 3, wherein neutrophils are present in the cell formulation such that at least 10% of the administered cells are neutrophils.

10. A use according to any one of claims 1 through 4, wherein the modified T cells and/or NK cells are administered subcutaneously in the presence of hyaluronidase.

11. A use according to any one of claims 1 or 3, wherein the modified T cells and/or NK cells are administered subcutaneously in a volume of between 1 ml and 5 ml of the cell formulation.

12. A use according to any one of claims 1 or 3, wherein the modified T cells and/or NK cells are introduced back into the subject within 14 hours from the time peripheral blood-derived product comprising the T cells and/or NK cells is drawn from the subject.

13. A use or method according to any one of claims 1 or 4, wherein the reaction mixture comprises an anticoagulant, and wherein the T cells and/or NK cells are in unfractionated whole blood from the subject when they are contacted.

14. A use or method according to any one of claims 1 or 3, wherein between 1 x 10^6 and 1 x 10^9 modified T cells and/or modified NK cells are delivered to the subject subcutaneously.

15. A use or method according to any one of claims 1 or 4 wherein the reaction mixture comprises at least 50% unfractionated whole blood by volume.

16. A use or method according to any one of claims 1 or 4, wherein the reaction mixture is in a closed cell processing system, wherein the contacting occurs when the reaction mixture is in a leukoreduction filter assembly in the closed cell processing system, and wherein the blood cells in the reaction mixture are total nucleated cells (TNCs).

17. A use or method according to claim 16, wherein the T cell and/or NK cell activation element is on the surface of the replication incompetent recombinant retroviral particles, the contacting is performed at between 2 °C and 15 °C, and optionally between 2 °C and 6 °C, for less than 1 hour, optionally after which the TNCs are incubated at between 32 °C and 42 °C for between 5 minutes and 4 hours, and optionally after which the modified T cells and/or NK cells are collected on a filter to form the cell formulation.

18. A use or method according to any one of claims 1 or 4, wherein the reaction mixture comprises at least 25% unfractionated whole blood by volume and an effective amount of an anticoagulant.

19. A use or method according to claim 18, wherein the anticoagulant is selected from the group consisting of acid citrate dextrose, EDTA, and heparin.

20. A use or method according to claim 18, wherein the anticoagulant is other than acid citrate dextrose.

21. A use or method according to claim 18, wherein the anticoagulant comprises an effective amount of heparin.

22. A use or method according to any one of claims 1 or 4, wherein the modified cells are modified T cells, and wherein the activation element is a T cell activation element, and wherein said T cell activation element is one or more of an anti-CD3 antibody, an anti-CD28 antibody, or a polypeptide that binds a mitogenic tetraspanin.

23. A use or method according to claim 22, wherein the T cell activation element is an anti-CD3 antibody, wherein the anti-CD3 antibody is bound to the membrane of the replication incompetent recombinant retroviral particles.

24. A use or method according to claim 23, wherein the membrane-bound anti-CD3 antibody is an anti-CD3 scFv or an anti-CD3 scFvFc.

25. A use or method according to claim 23, wherein the anti-CD3 antibody is bound to the membrane by a GPI anchor, wherein the anti-CD3 antibody is a recombinant fusion protein with a MuLV viral envelope protein, with or without a mutation at a furin cleavage site, or wherein the anti-CD3 antibody is a recombinant fusion protein with a VSV viral envelope protein.

26. A use or method according to any one of claims 1 or 4, wherein the replication incompetent recombinant retroviral particles are present in the reaction mixture at an MOI of between 2.5 and 5.

27. A use or method according to any one of claims 1 or 4, wherein the cell or cells are not subjected to a spinoculation during the method.

28. A use or method according to any one of claims 1 or 4, wherein the reaction mixture is in a blood bag during the contacting.

29. A use or method according to any one of claims 1 or 4, wherein the blood cells are in contact with a leukoreduction filter assembly in a closed cell processing system before the contacting, at the time the blood cells are contacted with recombinant retroviral particles, during the contacting comprising an optional incubating in the reaction mixture, and/or after the contacting comprising the optional incubating in the reaction mixture.

30. A use or method according to any one of claims 1 or 4, wherein the reaction mixture is in contact with a leukoreduction filter assembly in a closed cell processing system after the contacting.

31. A use or method according to any one of claims 1 or 4, wherein the unfractionated whole blood is other than cord blood.

32. A use or method according to any one of claims 1 or 4, wherein the contacting is performed for less than 12 hours, before retroviral particles that remain in suspension in the reaction mixture are separated away from cells.

33. A use, method, or cell formulation according to any one of claims 1 to 4, wherein the CAR is an MRB-CAR.

34. A use or method according to any one of claims 1 or 4, wherein the promoter operatively linked to a first transcriptional unit is constitutively active, and wherein the replication incompetent recombinant retroviral particles further comprise a second transcriptional unit operatively linked to an inducible promoter inducible in at least one of a T cell or an NK cell, wherein the first transcriptional unit and the second transcriptional unit are arranged in opposite directions,

and wherein the second transcriptional units encodes a lymphoproliferative element.

35. A use or method according to any one of claims 1 or 4, wherein the replication incompetent recombinant retroviral particles are lentiviral particles, and wherein the modified cell is a modified T cell.

36. A cell formulation according to claim 2, wherein the modified T cells and/or NK cells are genetically modified with the polynucleotide and the polynucleotide is a non-viral vector.

37. A cell formulation according to claim 2, wherein

a) at least 25%, or optionally at least 50%, of the modified T cells and/or NK cells in the cell formulation do not express one or more of the CAR or a transposase

b) at least 25%, or optionally at least 50%, of the modified T cells and/or NK cells in the cell formulation comprise a recombinant viral reverse transcriptase or a recombinant viral integrase;

c) at least 25%, or optionally at least 50%, of the modified T cells and/or NK cells in the cell formulation do not have the polynucleotide stably integrated into their genomes;

d) between 1% and 20%, or optionally between 5% and 15% of T cells and/or NK cells in the cell formulation are genetically modified; and/or

c) at least 25%, or optionally at least 50% of the modified T cells and/or modified NK cells in the cell formulation are viable.

38. A cell formulation according to claim 2, wherein at least 5% of the modified T cells and/or NK cells in the cell formulation are genetically modified.

39. A kit for modifying NK cells and/or T cells, comprising:

one or a plurality of containers containing polynucleotides comprising a first transcriptional unit operatively linked to a promoter active in T cells and/or NK cells, wherein the first transcriptional unit encodes a first polypeptide comprising a chimeric antigen receptor (CAR); and one or more accessory components selected from:

a) one or more containers containing a delivery solution adapted for subcutaneous or intramuscular administration;

b) one or more sterile syringes adapted for subcutaneous or intramuscular delivery of T cells and/or NK cells; and

c) one or a plurality of leukoreduction filtration assemblies.

40. The kit of claim 39, wherein the polynucleotides in the one or more containers containing the polynucleotides encoding the CAR, are located within replication incompetent recombinant retroviral particles.

41. The kit of claim 40, wherein the replication incompetent recombinant retroviral particles comprise a polynucleotide comprising one or more transcriptional units operatively linked to a promoter active in T cells and/or NK cells, wherein the one or more transcriptional units encode a first polypeptide comprising the CAR.

42. The kit of claim 40, wherein replication incompetent recombinant retroviral particles comprise on their surface, a binding polypeptide and a fusogenic polypeptide, wherein the binding polypeptide is capable of binding to a T cell and/or NK cell, and wherein the fusogenic polypeptide is capable of mediating fusion of a retroviral particle membrane with a T cell and/or an NK cell membrane.

43. The kit of claim 42, wherein surface of the replication incompetent recombinant retroviral particles further comprise an activation element, wherein the activation element is capable of activating a T cell and/or an NK cell.

44. The kit of claim 41, wherein the one or more containers containing the replication incompetent retroviral particles contain substantially pure, GMP grade, replication incompetent retroviral particles.

45. The kit of claim 44, wherein each container containing the replication incompetent retroviral particles contains a volume of between 0.1 ml and 10 ml, and between $1x10^6$ and $5x10^9$ retroviral particle Transducing Units.

46. The kit of claim 45, wherein the kit comprises one or more containers containing a delivery solution adapted for subcutaneous administration.

47. The kit of any one of claims 39 or 40, wherein the kit comprises one or a plurality of leukoreduction filtration assemblies.

48. The kit of any one of claims 39 or 40, wherein the kit comprises one or more sterile syringes adapted for subcutaneous delivery of T cells and/or NK cells.

49. The kit of any one of claims 39 or 40, wherein the kit comprises

a) one or more containers containing a delivery solution adapted for subcutaneous administration; and

b) one or more sterile syringes adapted for subcutaneous delivery of T cells and/or NK cells.

50. The kit of any one of claims 39 or 40, wherein the polynucleotides comprising the first transcriptional unit encoding a first polypeptide comprising a CAR, further comprise a second transcriptional unit encoding a second polypeptide comprising a lymphoproliferative element that comprises an intracellular signaling domain from a cytokine receptor that activates a JAK/ STAT pathway TRAF pathway.

51. The kit of claim 50, wherein the lymphoproliferative element is constitutively active and comprises BOX 1 and BOX 2 JAK-binding motifs and a STAT-binding motif comprising a tyrosine residue.

52. The kit of claim 51, wherein the lymphoproliferative element does not comprise a cytokine.

53. An isolated polynucleotide comprising a first transcriptional unit operably linked to an inducible promoter inducible in at least one of a T cell or an NK cell, and a second transcriptional unit operably

linked to a constitutive T cell or NK cell promoter, wherein the first transcriptional unit and the second transcriptional units are arranged divergently,

wherein at the first transcriptional unit encodes a lymphoproliferative element, and

wherein at the second transcriptional unit encodes a chimeric antigen receptor (CAR), wherein the CAR comprises an antigen-specific targeting region (ASTR), a transmembrane domain, and an intracellular activating domain.

54. A replication incompetent recombinant retroviral particle, comprising the isolated polynucleotide of claim 53.

55. The polynucleotide according to claim 53 or the replication incompetent recombinant retroviral particle of claim 54, wherein an insulator is located between the divergent transcriptional units.

56. A container comprising the isolated polynucleotide of claim 53 or the replication incompetent recombinant retroviral particle of claim 54, in a substantially pure formulation.

57. A kit, comprising the container of claim 56, and one or more of the following accessory components:

a) one or more containers containing a delivery solution adapted for, compatible with, and/or effective for, intravenous, subcutaneous and/or intramuscular administration;

b) one or more containers of hyaluronidase;

c) one or more blood bags;

d) one or more sterile syringes

e) one or a plurality of leukoreduction filtration assemblies;

f) one or more containers containing a solution or media adapted for transduction of T cells and/or NK cells;

g) one or more containers containing a solution or media adapted for rinsing T cells and/or NK cells;

h) one or more containers containing substantially pure nucleic acids, encoding a second CAR directed against a different target epitope on a different antigen found on a same target cancer cell as a first CAR;

i) one or more containers containing a cognate antigen for the first CAR; or

j) instructions, either physically or digitally associated with other kit components, for the use thereof, for modifying T cells and/or NK cells.

58. A genetically modified T cell or NK cell made by genetically modifying a T cell or NK cell according to a method comprising contacting the T cell or NK cell *ex vivo*, with an isolated polynucleotide of claim 53 or a replication incompetent recombinant retroviral particle of claim 54.

59. Use of a replication incompetent recombinant retroviral particle in the manufacture of a kit for modifying a T cell or an NK cell of a subject, wherein the use of the kit comprises:

contacting the T cell or the NK cell *ex vivo*, with the replication incompetent recombinant retroviral particle of claim 54, wherein said contacting facilitates association of the T cell or NK cell with the replication incompetent recombinant retroviral particle, thereby modifying the T cell or NK cell.

60. A method for modifying a T cell or an NK cell, comprising contacting the T cell or the NK cell *ex vivo*, with a replication incompetent recombinant retroviral particle of claim 54, wherein said contacting facilitates association of the T cell or NK cell with the replication incompetent recombinant retroviral particle, thereby modifying the T cell or NK cell.

61. The polynucleotide according to claim 53 or the replication incompetent recombinant retroviral particle of claim 54, wherein the constitutive T cell or NK cell promoter comprises an EF-1a promoter, PGK promoter, CMV promoter, MSCV-U3 promoter, SV40hCD43 promoter, VAV promoter, TCRbeta promoter, or UBC promoter.

62. The polynucleotide according to 53 or the replication incompetent recombinant retroviral particle of claim 54, wherein the inducible promoter comprises an NFAT-responsive promoter.

63. The polynucleotide or the replication incompetent recombinant retroviral particle of claim 62, wherein the NFAT-responsive promoter comprises at least 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, or 12 NFAT-binding sites, wherein the NFAT-binding sites comprise functional sequence variants which retain the ability to bind NFAT, and wherein the NFAT-responsive promoter comprises a minimal constitutive promoter with upstream NFAT-binding sites with a low level of transcription even in the absence of an inducing signal.

64. The polynucleotide according to claim 53 or the replication incompetent recombinant retroviral particle of claim 54, wherein the transcription of the lymphoproliferative element is less than 1/2, 1/4, 1/5 1/10, 1/25, 1/50, 1/100, 1/200, 1/250, 1/500, or 1/1,000 the level of transcription of the CAR in the absence of an inducing signal.

65. The replication incompetent recombinant retroviral particle according to claim 54, wherein the replication incompetent recombinant retroviral particle further comprises on its surface, an activation polypeptide, a binding polypeptide and a fusogenic polypeptide, wherein the activation polypeptide is capable of activating a T cell and/or an NK cell, wherein the binding polypeptide is capable of binding to a T cell and/or NK cell, and wherein the fusogenic polypeptide is capable of mediating fusion of a retroviral particle membrane with a T cell and/or an NK cell membrane.

66. The polynucleotide according to claim 53 or the replication incompetent recombinant retroviral particle of claim 54, wherein the lymphoproliferative element comprises an intracellular signaling domain from a cytokine receptor that activates a Janus kinase/ Signal Transducer and Activator of Transcription (JAK/ STAT) pathway or a tumor necrosis factor receptor (TNF-R) associated factor (TRAF) pathway.

67. The polynucleotide or the replication incompetent recombinant retroviral particle of claim 66, wherein the lymphoproliferative element is constitutively active and comprises Box 1 and Box 2 JAK binding motifs and a STAT-binding motif comprising a tyrosine residue.

68. The polynucleotide or the replication incompetent recombinant retroviral particle of claim 67, wherein the lymphoproliferative element does not comprise a cytokine.

What is claimed is:

1. A cell formulation for subcutaneous administration comprising:

a. modified lymphocytes and/or tumor infiltrating lymphocytes and wherein the cell formulation further comprises a recombinant hyaluronidase, or

b. modified lymphocytes and neutrophils, wherein at least 10% of the cells in the cell formulation are neutrophils.

2. The cell formulation of claim 1, wherein the cell formulation comprises the recombinant hyaluronidase, and wherein the volume of the cell formulation is between 2 and 1,000 ml.

3. The cell formulation of claim 2, wherein the concentration of the recombinant hyaluronidase is between 50 and 5,000 units/ml.

4. The cell formulation of claim 2, wherein the recombinant hyaluronidase is recombinant human hyaluronidase PH20.

5. The cell formulation of claim 2, wherein the cell formulation comprises T cells, and wherein at least 15% of the T cells in the cell formulation are genetically modified.

6. The cell formulation of claim 1, wherein the cell formulation comprises modified lymphocytes, and wherein the modified lymphocytes are derived from a peripheral blood sample.

7. The cell formulation of claim 1, wherein the modified lymphocytes are associated with a replication incompetent recombinant retroviral particle comprising a polynucleotide, or wherein the modified lymphocytes comprise a polynucleotide from a replication incompetent recombinant retroviral particle,

wherein the polynucleotide comprises one or more transcriptional units operatively linked to a promoter active in T cells and/or NK cells, and wherein at least one of the one or more transcriptional units encodes a polypeptide and/or inhibitory RNA.

8. The cell formulation of claim 7, wherein the one or more transcriptional units encode the polypeptide, and wherein the polypeptide is a chimeric antigen receptor, engineered T cell receptor, lymphoproliferative element, cytokine, or a cell tag.

9. The cell formulation of claim 7, wherein the replication incompetent recombinant retroviral particle further comprises an activation element on its surface.

10. The cell formulation of claim 7, wherein the replication incompetent recombinant retroviral particle is a lentiviral particle.

11. The cell formulation of claim 7, wherein:

a. at least 80% of the modified lymphocytes in the cell formulation do not express the polypeptide, and/or

b. at least 25% of the modified lymphocytes in the cell formulation comprise a recombinant viral reverse transcriptase or a recombinant viral integrase.

12. The cell formulation of claim 7, wherein the cell formulation comprises modified lymphocytes, and wherein at least 75% of the modified lymphocytes in the cell formulation do not have the polynucleotide stably integrated into their genomes.

13. The cell formulation of claim 1, wherein the modified lymphocytes comprise modified T cells and/or modified NK cells, wherein the cell formulation further comprises aggregates comprising modified T cells and/or modified NK cells that are at least 15 um in their smallest dimension, and wherein at least 10% of the cells in the cell formulation are aggregated.

14. The cell formulation of claim 1, wherein the modified lymphocytes comprise modified T cells and/or modified NK cells, and wherein the cell formulation comprises between 1×10^6 and 1×10^9 modified T cells and/or modified NK cells.

15. The cell formulation of claim 1, wherein cell formulation is contained within a subcutaneous delivery device.

16. The cell formulation of claim 1, wherein at least 60% of the cells are viable.

17. The cell formulation of claim 1, wherein the cell formulation further comprises up to 50 mg/ml albumin and less than 7% DMSO, wherein the pH is adjusted to between 6.5 to 8.0.

18. The cell formulation of claim 1, wherein the cell formulation further comprises:

a. between 0.5 and 6 mg/ml sodium chloride (NaCl),

b. between 0.5 and 6 mg/ml sodium gluconate ($C_6H_{11}NaO_7$),

c. between 0.3 and 4 mg of sodium acetate trihydrate ($C_2H_3NaO_2 \cdot 3H_2O$),

d. between 0.3 and 4.5 mg/ml potassium chloride (KCl), and

e. between 0.03 to 0.4 mg/ml magnesium chloride ($MgCl_2 \cdot 6H_2O$).

19. Use of a replication incompetent recombinant retroviral particle in the manufacture of a kit for administering modified T cells and/or NK cells to a subject, comprising:

a. contacting T cells and/or NK cells ex vivo with replication incompetent recombinant retroviral particles comprising a polynucleotide encoding a transgene, wherein the recombinant retroviral particles modify the T cells and/or NK cells;

b. collecting the modified T cells and/or NK cells to form a cell formulation comprising a suspension of the modified T cells and/or NK cells; and

c. administering the cell formulation to a subject subcutaneously,

wherein at least 25% of the modified T cells and/or NK cells in the cell formulation do not have the polynucleotide stably integrated into their genomes.

20. The use of claim 19, wherein the use further comprises collecting a peripheral blood sample, and wherein the cell formulation comprises monocytes, wherein at least 10% of the monocytes present in the blood sample are present in the cell formulation.