

Breast Cancer Research Program

Women's Cancer Developmental Therapeutics (WCDT) Program

WCDT Program Nurse Navigator	Brandi Welker	720-848-9302	brandi.welker@uchealth.org
Breast Cancer Research Team Manager	Brad McKay	720-848-0609	brad.mckay@ucdenver.edu
Molecular Oncology Therapeutics (formerly T3) Team Manager	Courtney Newbold	720-848-0653	courtney.newbold@ucdenver.edu
Phase I Research Team New Patient Intake Coordinator	Amanda Lark	720-848-0678	Amanda.Lark@ucdenver.edu
	Amanda Siedem	720-848-0052	Amanda.Siedem@ucdenver.edu
Radiation Oncology Research Team Manager	Robyn Swing	720-848-0607	robyn.swing@ucdenver.edu

Contact WCDT Program Nurse Navigator for patient referral or to request additional information.

[Visit our website to request more information or send us a referral:](#)

<http://tinyurl.com/WCDTProgram>

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Metastatic Breast Cancer Clinical Trials

A. ER+ HER2-

a. Any Line

16-1001 A Phase 2 Trial of Fulvestrant (ER antagonist) plus Enzalutamide (AR Inhibitor) in ER+/HER2- Advanced Breast Cancer

(NCT02953860) PI Elias, Study Coordinator: Stephanie Armstead

Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)

Lone Tree Research Team (Brown)

- Any number of prior lines of therapy, Measurable disease by RECIST
- Metastatic, candidate for fulvestrant, may have started fulvestrant within 3 months
- Postmenopausal or ovarian suppression
- Must have disease that can be biopsied, No history of seizures, treated brain mets allowed

b. First Line

16-0148 Phase 1B Study of Gedatolisib (PI3K/mTOR inhibitor) in Combination with Palbociclib (CDK4 & CDK6 inhibitor) and Either Letrozole (aromatase inhibitor) or Fulvestrant (ER antagonist) in Metastatic or Locally Advanced/Recurrent Breast Cancer

Pfizer (NCT02684032) PI: Kabos, Study Coordinator: Kyrie Dailey

Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)

- Arm A first-line endocrine-based therapy only arm open
- Postmenopausal or Ovarian Suppression, ER+HER2-,
- measurable disease required
- No prior mTOR inhibitor or PI3K inhibitor, treated brain mets ok
- No more than 1 prior line of treatment for advanced metastatic disease

c. First or Second Line

17-2208 A Phase Ia/Ib, Multicenter, Open-Label, Dose Escalation, Dose Expansion Study of GDC-9545 (SERD) Alone or in Combination with Palbociclib (CDK4 & CDK6 inhibitor) and/or LHRH Agonist in Patients with Locally Advanced or Metastatic ER Positive Breast Cancer

(NCT03332797) PI: Kabos, Study Coordinator: Stephanie Armstead

Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)

- Dose Expansion Cohorts A1 or A3 (post-menopausal) and Cohorts A2 and A4 (pre/perimenopausal)
- Locally recurrent or metastatic breast cancer ER+HER2-
- Measurable or Evaluable Disease, treated brain mets are ok
- No more than 1 prior line of treatment for advanced or metastatic disease
- Metastatic recurrence on adjuvant endocrine therapy
- Advanced or metastatic ER+HER2- breast cancer that has recurred or progressed while being treated with adjuvant endocrine therapy for a duration of at least 24 months and/or endocrine therapy in the incurable, locally advanced, or metastatic setting and derived benefit from therapy (ie, tumor response or stable disease for at least 6 mos)

B. HER2+

a. Second or Third Line

16-1661 Phase Ib/II Open-Label Single Arm Study to Evaluate Safety and Efficacy of Tucatinib in Combination with Palbociclib (CDK4 & CDK6 inhibitor) and Letrozole (aromatase inhibitor) in Subjects with Hormone Receptor Positive and HER2-Positive Metastatic Breast Cancer

Tucatinib (NCT03054363) PI Shagisultanova, Study Coordinator: Heather Nelson

Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)

- Post-menopausal or ovarian suppression, ER+HER2+
- At least two approved HER2-targeted agents (trastuzumab, pertuzumab, or TDM-1) in the course of their disease with at least 1 line of prior HER2-targeted therapy in the metastatic setting, (see protocol for exceptions)
- Up to 2 lines of prior endocrine therapy in the metastatic setting are allowed. Prior adjuvant and/or neoadjuvant endocrine regimens are allowed and not counted towards this limit
- Measureable or Evaluable Disease

C. TNBC

a. First or Second line

16-2105 SWOG S1416 Phase II Randomized, Placebo-Controlled Trial of Cisplatin (alkylating antineoplastic) with or Without ABT-888 (Veliparib—PARP Inhibitor) in Metastatic TNBC and/or BRCA-Mutation-Associated Breast Cancer

(NCT02595905) PI: Mayordomo, Study Coordinator: Stephanie Armstead

Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)

Breast Cancer Research Team North (Medgyesy, Datko)

Breast Cancer Research Team South (Njiaju)

- TNBC or ER+HER2- with deleterious BRCA mutation
- 0-1 prior lines of therapy
- Measurable or non-measurable disease
- CNS mets permitted if patient meets additional criteria → Brain Mets Cohort
- No prior treatment with cisplatin or PARP inhibitors

b. Any Line

17-1099 Phase 2 Randomized Study of ABT-888 (Veliparib) and Atezolizumab Alone or with Homologous DNA Repair (HDR) TNBC

(NCT02849496) PI: Afghahi, Study Coordinator: Gloria Crawford

Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)

- BRCA 1/2 mutation present, Her2 negative
- No prior treatment with PARP inhibitors or anti-PD-1/anti-PD-L1 antibodies
- ECOG 0-2
- Measurable disease by RECIST
- Asymptomatic, treated brain mets allowed
- No limit on prior lines of therapy

D. Multiple Subtypes

15-0801 My Pathways: An Open-Label Phase IIA Study Evaluating Trastuzumab (HER2/neu inhibitor)/Pertuzumab (HER2 inhibitor), Erlotinib (EGFR/TK inhibitor), Vemurafenib (B-Raf inhibitor)/Cobimetinib (MEK inhibitor), Vismodegic (Hedgehog inhibitor), Alectinib (ALK inhibitor), and Atezolizumab (PD-L1 binder) in Patients who have Advanced Solid Tumors with Mutations or Gene Expression Abnormalities Predictive of Response to one of these Agents

Genetech (NCT02091141) PI: Lam, Study Coordinator: Tate Closson-Niese
Molecular Oncology Research Team Anschutz Breast Clinic (Diamond, Elias, Mayordomo)

- Arm with atezolizumab in patients with elevated tumor mutation burden (>10 mutations/Mb as determined by any CLIA validated assay) open
- Excludes active or untreated brain mets. Must be stable for 1 month
- Measurable disease
- ECOG 0-1
- No available therapies that will convey clinical benefit or no suitable treatment options per treating physician's judgement

15-1111 EAY131 Molecular Analysis for Therapy Choice. NCI-MATCH. (Targeted drugs for specific molecular aberrations)

(NCT02465060) PI Lieu, Study Coordinator: Lauren Draper
Molecular Oncology Research Team Anschutz Breast Clinic (Diamond, Elias, Mayordomo)

- At least one prior line and no other therapy prolonging survival
- Measurable disease, treated brain mets allowed
- Biopsy required and if mutation then assigned to arm
- Arms: EGFR mut, MET ex 14 sk, EGFR T790M, ALK transloc, ROS1 transloc, mTOR mut, TSC1/2 mut, GNAQ/GNA11, SMO/PTCH1, cKIT mut, NTRK fus. Please speak with coordinator for details on open arms.

E. Subcutaneous Metastasis Amenable to Intratumor Injection

17-0074 A Phase 1 Open-Label, Multicenter, Dose Escalation Study of mRNA-2416, a Lipid Nanoparticle Encapsulated mRNA encoding Human OX40L, for Intratumoral Injection to Patients with Advanced Malignancies

Moderna (NCT03323398), PI Jimeno, Study Coordinator: Anne Martin
Phase I Research Team/Clinic Anschutz (Diamond)

- Tumor Types: All Comers with Subcutaneous or cutaneous mass for injection
- Check with coordinator for slots

F. Radiation Studies

15-0136 A Phase IIR/III Trial of Standard of Care Therapy with or without Stereotactic Body Radiotherapy (SBRT) and/or Surgical Ablation for Newly Oligometastatic Breast Cancer

(NCT02364557) PI Rabinovitch, Study Coordinator: Chelsea Schaefer
Rad Onc Research Team Anschutz (Fisher, Rabinovitch)
Rad Onc Research Team North
Rad Onc Research Team South

- ≤ 4 metastases seen on standard imaging within 60 days prior to registration when all metastatic disease is located within the following sites: peripheral lung; osseous (bone); spine; central lung; abdominal-pelvic **OR**
- ≤ 2 metastases seen on standard imaging within 60 days prior to registration when any one metastasis is located in one of the following sites: liver; mediastinal/cervical lymph node; At least 1 pathologically confirmed visualized on CT or PET/CT.

Stage I-III Breast Cancer Clinical Trials

A. Multiple subtypes

a. Neoadjuvant

10-0374 Investigation of Serial Studies to Predict Your Therapeutic Response with Imaging and Molecular Analysis 2

I-SPY 2 (NCT01042379) PI: Elias, Study Coordinator: Gloria Crawford

Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)

- All Comers
- Imaging and Molecular Analysis
- Any HER2, ER/PR status
- Stage II or III or T4, any N, M0 or Regional Stage IV
- ≥ 2.5 IBC
- Measurable disease by RECIST

b. Adjuvant

14-1534 NRG B55 A Randomized, Double-Blind, Parallel Group, Placebo-Controlled Multi-Centre Phase III Study to Assess the Efficacy and Safety of Olaparib (PARP inhibitor) Versus Placebo as Adjuvant Treatment in Patients with Germline BRCA1/2 Mutations and High Risk HER2 Negative Primary Breast Cancer Who Have Completed Definitive Local Treatment and Neoadjuvant or Adjuvant Chemotherapy

(NCT02032823) PI: Borges, Study Coordinator: Heather Nelson

Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)

Breast Cancer Research Team North (Medgyesy, Datko)

- BRCA mutation
- If surgery first and adjuvant chemo: TNBC node positive OR T2+ node negative, ER/PR+ HER2 – 4+ pathologically confirmed lymph nodes
- If neoadjuvant chemo: TNBC no pCR, ER/PR+HER2- non pCR AND CPS&EG score ≥ 3
- No prior PARPi exposure

15-2078 Study Evaluating the Pregnancy Outcomes and Safety of Interrupting Endocrine Therapy for Young Women with Endocrine Responsive Breast Cancer who Desire Pregnancy

POSITIVE (NCT02308085) PI Borges, Study Coordinator: Heather Nelson

Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)

- ER+ and/or PR+
- Stage I-III

- 18 – 42 years of age
- Must have received 18-30 months endocrine therapy and enrolled within 1 month of stopping
- Desire for pregnancy

16-1240 Randomized Phase III Trial Evaluating the Role of Weight Loss in Adjuvant Treatment of Overweight and Obese Women with Early Breast Cancer

BWEL (NCT02750826) PI: Brown, Study Coordinator: Lisa Lopez

Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)

Lone Tree Research Team (Brown)

Breast Cancer Research Team North (Medgyesy, Datko)

- HER2-, Any ER/PR, diagnosed in last 12 months
 - ER- and PR-: T2 or T3 N0, T0-3N1-3. Note: Patients with T1, N1mi disease are NOT eligible.
 - ER+ and/or PR+: T0-3N1-3 or T3N0. Note: Patients with T1-2, N1mi disease are NOT eligible
- No insulin dependent DM, IBS or other digestive problems that interfere with study diet, no health issues that preclude physical activity
- BMI ≥ 27

16-2437 (Co-Op): A Randomized Phase III Double Blinded Placebo Controlled Trial of Aspirin as Adjuvant Therapy for Node Positive HER2 Negative Breast Cancer: THE ABC TRIAL

(NCT02927249) PI: Borges, Study Coordinator: Kari Corby

Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)

Lone Tree Research Team (Brown)

Breast Cancer Research Team North (Medgyesy, Datko)

Breast Cancer Research Team South (Njiaju)

- Stage II or III, no recurrence, diagnosed within the last 12 months
- HER2-, any ER/PR status okay
- No history of GI bleed, stroke, ulcers, afib, MI, grade 4 HTN, or other cancer in last 5 years

17-1750 NRG BR005 Tumor Bed Biopsies in Predicting Pathologic Response in Patients with Clinical/Radiologic Complete Response after Neoadjuvant Chemotherapy in Order to Explore the Feasibility of Breast Conserving Treatment without Surgery

(NCT03188393) PI: Ahrendt, Study Coordinator: Gloria Crawford

- T1-T3, stage II and IIIA invasive ductal carcinoma and who have completed 8 wks neoadjuvant chemotherapy with a clinical complete response (by clinical examination)
- Must have achieved a complete or near complete radiologic tumor response on breast imaging with mammogram, ultrasound, and MRI
- Patients must be undergoing breast conserving therapy

B. ER+ HER2-

a. Neoadjuvant

18-1211 Study of Pembrolizumab (MK-3475) Versus Placebo in Combination With Neoadjuvant Chemotherapy & Adjuvant Endocrine Therapy in the Treatment of Early-Stage Estrogen Receptor-Positive, Human Epidermal Growth Factor Receptor 2-Negative (ER+/HER2-) Breast Cancer (MK-3475-756/KEYNOTE-756)

(NCT03725059) PI: Diamond, Study Coordinator: Stephanie Armstead

Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)

- Has a localized invasive breast ductal adenocarcinoma, confirmed by the local pathologist, that includes either T1c-T2 (tumor size ≥ 2 cm), clinical node stage (cN)1-cN2, or T3-T4, cN0-cN2. Note: Inflammatory breast cancer is allowed.
- Centrally confirmed ER+/HER2-, grade 2 or 3 with Ki67 $\geq 30\%$
- Male or female
- N3 excluded

16-1657 ALTERNATE Approaches for Clinical Stage II or III Estrogen Receptor Positive Breast Cancer Neoadjuvant Treatment in Postmenopausal Women: A Phase III Study

(NCT01953588) PI: Borges, Study Coordinator: Heather Nelson

Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)

Lone Tree Research Team (Brown)

Breast Cancer Research Team North (Medgyesy, Datko)

Breast Cancer Research Team South (Njiaju)

- Fulvestrant (ER antagonist) + anastrozole (aromatase inhibitor)
- HER2- / ER+ only
- Clinical T2 – T4c, any N, M0
- Post-menopausal
- High risk Ki67 greater than 10%

16-1042 Randomized Phase II Trial of Preoperative Fulvestrant (ER antagonist) with or without Enzalutamide (AR Inhibitor) in ER+/HER2- Breast Cancer

(NCT02955394) PI: Elias, Study Coordinator: Gloria Crawford

Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)

Lone Tree Research Team (Brown)

- Stage at least T2 or greater, postmenopausal or ovarian suppression
- No history of seizures, no anti-coags
- Must undergo biopsies

b. Adjuvant

13-1448 S1207 Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the use of Adjuvant Endocrine Therapy +/- One Year of Everolimus (mTOR inhibitor) in Patients with High-Risk Hormone Receptor+ HER2- Breast Cancer

(NCT01674140) PI: Elias, Study Coordinator: Heather Nelson

Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)

Lone Tree Research Team (Brown)

- HER2- and ER/PR +
- Must have received and completed neoadjuvant or adjuvant chemotherapy
- Must be high risk as defined by: 4+ nodes, 1+ positive nodes after neoadjuvant chemo, 1-3+ nodes and oncotype > 25, mammoprint high, or high grade, node negative with T2+ and oncotype > 25 or high mammoprint.

C. TNBC

b. Adjuvant

16-2594 S1418 A Randomized Phase III Trial to Evaluate the Efficacy and Safety of MK-3475 (Pembrolizumab, PD-1 inhibitor) for TNBC with \geq 1cm Residual Invasive Cancer or Positive Lymph Nodes (ypN+) After Neoadjuvant Chemotherapy

(NCT02954874) PI: Elias, Study Coordinator: Stephanie Armstead

Breast Cancer Research Team Anschutz (Afghani, Borges, Diamond, Elias, Kabos, Mayordomo, Shagisultanova)

Lone Tree Research Team (Brown)

Breast Cancer Research Team North (Medgyesy, Datko)

Breast Cancer Research Team South (Njiaju)

- TNBC s/p neoadjuvant chemo residual disease > 1 cm and/or node positive
- Addition of adjuvant chemo allowed
- No prior immunotherapy
- Residual disease
- Radiation allowed but randomization should occur before starting

D. Radiation

13-2454 A Randomized Phase III Clinical Trial Evaluating Post-Mastectomy Chest Wall and Regional Nodal XRT and Post-Lumpectomy Regional Nodal XRT in Patients with Positive Axillary Nodes Before Neoadjuvant Chemotherapy who Convert to Pathologically Negative Axillary Nodes After Neoadjuvant Chemotherapy

(NCT01872975) PI: Rabinovitch, Study Coordinator: Chelsea Schaefer

Rad Onc Research Team Anschutz (Fisher, Rabinovitch)

Rad Onc Research Team North

Rad Onc Research Team South

- Previous treatment with anthracycline or taxane regimen, 8 weeks minimum
- HER2+ must have received neoadjuvant anti-HER2 therapy
- Lumpectomy or mastectomy with negative axillary nodes at that time

18-0627 Phase III Randomized Trial of Hypofractionated Post Mastectomy Radiation With Breast Reconstruction

(NCT03414970) PI: Rabinovitch, Study Coordinator: Chelsea Schaefer, Tess Santangelo

Rad Onc Research Team Anschutz (Fisher, Rabinovitch)

- Mastectomy and have involved lymph nodes per pathology

- Histologically confirmed invasive carcinoma of the breast - ductal, lobular, mammary, medullary or tubular allowed
- Eligible women include Final AJCC Stage IIa-IIIa (pathologic stage T0N1a-2a, T1N1a-2a, T2N1a-2a, T3N0-2a, all M0 status) Pathological stage for all patients not receiving neoadjuvant chemotherapy. Higher of the clinical or pathological T and N stage, if receiving neoadjuvant chemotherapy. Patients with pathological N0 at the time of mastectomy are only eligible if biopsy-proven clinically N1 or N2 disease is documented prior to induction chemotherapy.
- No significant post mastectomy complications requiring unplanned re-operation or admission for IV antibiotics

There are additional Phase I all comer trials available, please contact the Nurse Navigator for assistance.

Breast Providers	Location	Contact WCDT Navigator	Email
Anosheh Afghahi, MD	Anschutz	720-848-9302	Anosheh.Afghahi@ucdenver.edu
Virginia Borges, MD	Anschutz & Lone Tree	720-848-9302	Virginia.Borges@ucdenver.edu
Regina Brown, MD	Lone Tree	720-848-9302	Regina.Brown@ucdenver.edu
Jennifer Diamond, MD	Anschutz	720-848-9302	Jennifer.Diamond@ucdenver.edu
Anthony Elias, MD	Anschutz	720-848-9302	Anthony.Elias@ucdenver.edu
Christine Fisher, MD – Radiation	Anschutz	720-848-9302	Christine.Fisher@ucdenver.edu
Peter Kabos, MD	Anschutz	720-848-9302	Peter.Kabos@ucdenver.edu
Jose Mayordomo, MD	Anschutz	720-848-9302	Jose.Mayordomo@ucdenver.edu
Sameer Nath, MD - Radiation	Anschutz	720-848-9302	Sameer.Nath@ucdenver.edu
Rachel Rabinovitch, MD - Radiation	Anschutz	720-848-9302	Rachel.Rabinovitch@ucdenver.edu
William Robinson, MD	Anschutz	720-848-9302	William.Robinson@ucdenver.edu
Elena Shagisultanova, MD	Anschutz	720-848-9302	Elena.Shagisultanova@ucdenver.edu

Melony Avella-Howell, NP	Anschutz - GI/Phase I	720-848-9302	Melony.Avella-Howell@ucdenver.edu
Colleen Dougherty-Gray, NP	Anschutz	720-848-9302	Colleen.Dougherty-Gray@ucdenver.edu
Laurri Jones, NP	Anschutz	720-848-9302	Laurri.Jones@ucdenver.edu
Breast CRCs	Office	Pager	Email
McKay, Brad - Manager	720-848-0609	303-266-0022	Brad.Mckay@ucdenver.edu
Shive, Nadia - Supervisor	720-848-1386	303-266-5374	Nadia.Shive@ucdenver.edu
Armstead, Stephanie	720-848-0729	303-266-4520	Stephanie.Armstead@ucdenver.edu
Corby, Kari	720-848-0675	303-266-1038	Kari.Corby@ucdenver.edu
Crawford, Gloria	720-848-0735	303-266-4909	Gloria.Crawford@ucdenver.edu
Dailey, Kyrie	720-848-9456	303-266-4695	Kyrie.Dailey@ucdenver.edu
Lopez, Lisa—Lone Tree	720-553-1133	303-266-2589	Lisa.Lopez@ucdenver.edu
Nelson, Heather	720-848-9351	303-266-4314	Heather.L.Nelson@ucdenver.edu
Breast CRC On Call		303-266-6404	
Molecular Oncology CRCs	Office	Pager	Email
Wynfield, Anna - Supervisor Molecular Oncology	720-848-5278	303-266-3369	Anna.Wynfield@ucdenver.edu
Closson-Niese, Tate	720-848-0669	303-266-1829	Tate.Closson-Niese@ucdenver.edu
Draper, Lauren	720-848-7341	303-266-1084	Lauren.Draper@ucdenver.edu
Pearson, Olivia	720-848-9382	303-266-1277	Olivia.Pearson@ucdenver.edu
Phase I CRCs	Office	Pager	Email
Lark, Amanda	720-848-0678		Amanda.Lark@ucdenver.edu
Siedem, Amanda	720-848-0052		Amanda.Siedem@ucdenver.edu
Freas, Elizabeth	303-724-8632	303-266-2328	Elizabeth.Freas@ucdenver.edu
Martin, Anne	720-848-0657	303-266-0231	Anne.C.Martin@ucdenver.edu
Rippke, Sarah	720-848-0685	303-266-1710	Sarah.Rippke@ucdenver.edu
Wells, Tara RN	720-848-0755	303-266-1654	Tara.Wells@ucdenver.edu
Phase I On Call		303-266-2328	
Radiation CRCs	Office	Pager	Email

Swing, Robyn – Manager	720-848-0607	303-266-7223	Robyn.Swing@ucdenver.edu
Withrow, Suzanne – Supervisor	720-848-0593	303-266-6227	Suzanne.Withrow@ucdenver.edu
Santangelo, Tess	720-848-9398	303-266-5454	Tess.Santangelo@ucdenver.edu
Schaefer, Chelsea	720-848-0608	303-266-3662	Chelsea.Schaefer@ucdenver.edu