

THE BELMONT REPORT

2IILFH RI WKH 6HFUHWDU\

(WKLFDO 3ULQFLSOHV DQG *XLGHOLQHV IRU
6XEMHFWV RI 5HVHDFK

7KH 1DWLRQDO &RPPLVVLRQ IRU WKH 3URWH
%LRPHGLFDO DQG %HKDYLRUDO 5HVHDFK

\$SULO

AGENCY: 'HSDUWPHQW RI +HDOWK (GXFDWLRQ DQG :HOIDUH

ACTION: 1RWLFH RI 5HSRUW IRU 3XEOLF &RPPHQW

SUMMARY: 2Q -XO\ WKH 1DWLRQDO 5HVHDFK \$SULO 6XEQWR ODZ WKHUH E\ 1DWLRQDO &RPPLVVLRQ IRU WKH 3URWHFWLRQ RI +XPDQ 6XEMHFWV RI %LRPHGLFDO FKDUJHV WR WKH &RPPLVVLRQ ZDV WR LGHQWLI\ WKH EDVLF HWKLFDO SULQFLS DQG EHKDYLRUDO UHVHDFK LQYROYLQJ KXPDQ VXEMHFWV DQG WR GHYHORS J VXFK UHVHDFK LV FRQGXFWHG LQ DFFRUGDQFH ZLWK WKRVH SULQFLSOHV ,Q GLUHFWHG W\RWPRQV &RQGLULHV EHWZHHQ ELRPHGLFDO DQG EHKDYLRUDO UHVH SUDFWLFH R(ii)MICHLELOH RI DVVHVVPHQW IRU LWLVND LQ WKH GHWHUPLQDWLRQ UHVHDFK LQYROYLQJ DSSUR SULDWH JXLGHOLQHV IRU WKH VHOHFWLRQ RI KXP VXFK UHVHDFK QDWXUH DQG GHILQLWLRQ RI LQIRUPHG FRQVHFW LQ YDULR

7KH %HOPRQW 5HSRUW DWWHPSWV WR VXPPDULJH WKH EDVLF HWKLFDO SULQFL LWV GHOLEHUDWLRQV ,W LV WRXSRXSHURZWRIRGIDQXQWLRQMLWKDW ZHUH KHOG WKH 6PLWKVRQLDQ ,QVWLWXWLRQ V %HOPRQW &RQIHUHQFH &HQWHU VXSSOHPH &RPPLVVLRQ WKDW ZHUH KHOG RYHU D SHULRG RI QHDUO\ IRXU \HDUV ,W LV D JXLGHOLQHV WKDW VKRXOG DVVLVW LQ UHVROYLQJ WKH VDOXLFDO SUREOHPV W

WKH 6XSHULQWHQGHW RI 'RFXPHQWV 86 *RYHUQPHQW 3ULQWLQJ 2IILFH :DV

8QOLNH PRVW RWKHU UHSRUWV RI WKH &RPPLVVLRQ VSKALVFOURRQPHBHQSDWLG DGPLQLVWUDWLYH DFWLRQ E\ WKH 6HFUHWDU\ RI +HDOWK (GXFDWLRQ DQG :HOIDUH WKH %HOPRQW 5HSRUW EH DGRSWHG LQ LWV HQWLUHW\ DV D VWDWHPHQW RI SXEOLF FRPPHQW RQ WKLV UHFRPPHQGDWLRQ

1DWLRQDO &RPPLVVLRQ IRU WKH 3URWHFWLI
%LRPHGLFDO DQG %HKDYLRUDO 5HVHDUFK

0HPEHUV RI WKH &RPPLVVLRQ

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'HFHDVHG

7DEOH RI &RQWHQWV

(WKLFDO 3ULQFLSOHV DQG *XLGHOLQHV IRU 5HVHDUFK ,QYR

\$ %RXQGDULHV %HWZH HQ 3UDFWLFH DQG 5HVHDUFK

% %DVLF (WKLFDO 3ULQFLSOHV

5HVSHFW IRU 3HUVRQV

%HQHILFHQFH

-XVWLFH

& \$SSOLFDFWLRQV

,QIRUPHG &RQVHQW

\$VVHVVPHQW RI 5LVN DQG %HQHILWV

6HOHFWLRQ RI 6XEMHFWV

(WKLFDQ 3ULQFLSOHV *XLGHOLQHV IRU 5HVHDFK

6FLHQWLILF UHVHDFK KDV SURGXFHG VXEVDQWLDO VRFDO EHQHILWV TXHVWLRQV 3XEOLF DWWHQWLRQ ZDV GUDZQ WR WKHVH TXHVWLRQV E\ UELRPHGLFDO H[SHULPHQWV HVSHFLDOO\ GXULQJ WKH 6HFRQG :RUOG :DUWKH 1XUHPEHUJ FRGH ZDV GUDIWHG DV D VHW RI VWDQGDUGV IRU MXGJLF FRQGXFWHG H[SHULPHQWV RQ FRQFHQWUDWLRQ FDPS SULVRQHUV 7KLV PDQ\ ODWHU LQVHQVHG WR DVVXUH WKDW UHVHDFK LQYROYLQJ KXPDQV HWKLFDO PDQQHU

7KH FRGHV FRQVLVW RI UXOHV VDPH JHQHUDO RWKHUV VSHFLILF WKDW UHVHDFK LQ WKHLU ZRUN 6XFK UXOHV RIWHQ DUH LQDGHTXDWH WRFRYFRQIOLFW DQG WKH\ DUH IUHTXHQWO\ GLILFXOW WR LQWHUSUHW RU DSSURQ ZKLFK VSHFLILF UXOHV PD\ EH IRUPXODWHG FULWLFL]HG DQG LQWHUS

7KUH SULQFLSOHV RU JHQHUDO SUHVFULSWLYH MXGJPHQWV WKDW DUH DUH LGHQWLILHG LQ WKLV VWDWPHQW 2WKHU SULQFLSOHV PD\ DOVR EH KRZHYHU DQG DUH VWDWHG DW D OHYHO RI JHQHUDOL]DWLRQ WKDW VKR LQWHUHVWHG FLWL]HQV WR XQGHUVWDQGLQJ RQH RWKHU DQVXHV MLQWHUHV SULQFLSOHV FDQQRW DOZD\V EH DSSOLHG VR DV WR UHVROYH EH\RQG GLUHFWLYH LV WR SURYLGH DQ DQDO\WLFDO IUDPHZRUN WKDW ZLOO JXLG UHVHDFK LQYROYLQJ KXPDQ VXEMLFWV

7KLV VWDWPHQW FRQVLVWV RI D GLVWLQFWLRQ EHWZHHQ UHVHDFK DQ HWKLFDO SULQFLSOHV DQG UHPDUNV DERXW WKH DSSOLFDWLRQ RI WKHV

3DUW \$ %RXQGDULHV %HWZHHQ 3UDFWLFH 5HVHDFK

A. Boundaries Between Practice and Research

,W LV LPSRUWDQW WR GLVWLQJXLVK EHWZHHQ ELRPHGLFDO DQG EHKDYLR RI DFFHSWHG WKHUDS\ RQ WKH RWKHU LQ RUGHU WR NQRZ ZKDW DFWLYL RI KXPDQ VXEMLFWV RI UHVHDFK 7KH GLVWLQFWLRQ EHWZHHQ UHVHDFK RIWHQ RFFXU WRJHWKHU DV LQ UHVHDFK GHVLJQH WR HYDOXDWH D W IURP VWDQGDUG SUDFWLFH DUH RIWHQ FDOOHG H[SHULPHQWDO ZKHQ W FDUHIXOO\ GHILQH

)RU WKH PRVW SDUW WKH WHUP SUDFWLFH UHIV WR LQWHUYHQWLRQ EHLQJ RI DQ LQGLYLGXDO SDWLHQW RU FOLHQW DQG WKDW KDYH D UHDFWPHGLFDO RU EHKDYLRUDO SUDFWLFH LV WR SURYLGH GLDJQRVLV SUHYHG LQGLYLQDO FRQWUDV WKH WHUP UHVHDFK GHVLJQDWHV DQ DFWLYL FRQFOXVLRQV WR EH GUDZQ DQG WKHUH\ WR GHYHORS RU FRQWULEXWH H[DPSOH LQ WKHRULHV SULQFLSOHV DQG VWDWPHQWV RI UHODWLRQV SURWRFRO WKDW VHW IRUWK DQ REMHFVLYH DQG D VHW RI SURFHGXUHV

:KHQ D FOLQLFLDQ GHSDUWV LQ D VLJQLILFDQW ZD\ IURP VWDQGDUG RU D DQG RI LWVHOI FRQVLWXWH UHVHDFK 7KH IDFV WKDW D SURFHGXUHV RI RU GLIIHUHQW GRHV QRW DXWRPDWLFDOO\ SODFH LW LQ WKH FDWHJRU\

GHVFULSWLRQ VKR~~POG~~HKR~~ZH~~YEMHFW RI IRUPDO UHVHDFK DW DQ HDUO\
ZKHWKHU WKH\ DUH VDIH DQG HIIHFWLYH 7KXV LW LV WKH UHVSQRVLELO
H[DPSOH WR LQVLVW WKDW D PDMRU LQQRWDWLRQ >E@ LQFRUSRUDWHG LG

5HVHDFK DQG SUDFWLFH PD\ EH FDUULHG RQ WRJHWKHU ZKHQ UHVHDFK
HIILFDF\ RI D WKHUDS\ 7KLV QHGH QRW FDXVH DQ\ FRQIXVLRQ UHJDUGLO
UHYL~~MZH~~JHQHUDO UXOH LV WKDW LI WKHUH LV DQ\ HOHPHQW RI UHVHDFK
UHYLHZ IRU WKH SURWHFWLRQ RI KXPDQ VXEMHFW

3DUW % %DVLF (WKLFDO SULQFLSOHV

B. Basic Ethical Principles

7KH H[SUHVVLRQ EDVLF HWKLFDO SULQFLSOHV UHIHUV WR WKRVH JHQHUDO
IRU WKH PDQ\ SDUWLFXODU HWKLFDO SUHVFULSWLRQV DQG HYDOXDWLRQ
DPRQJ WKRVH JHQHUDOO\ DFFHSWHG LQ RXU FXOWXUDO WUDGLWLRQ DUH
LQYROYLQJ KXPDQ VXEMHFW WKH SULQFLSOHV RI UHVSHFW RI SHUVRQV

5HVSHFW IRU SHUVRQV SHUVRQV LQFRUSRUDWLRQV LQVWLWXWV
WKDW LQGLYLGXDOV VKRXOG EH WUHDWHG DV DXWRQRPRXV DJHQWV DQG
DXWRQRP\ DUH HQWLWOHG WR SURWHFWLRQ 7KH SULQFLSOH RI UHVSHFW
UHTXLUHPHQWV WKH UHTXLUHPHQW WR DFNQRZOHGJH DXWRQRP\ DQG WK
GLPLQLVKHG DXWRQRP\

\$Q DXWRQRPRXV SHUVRQ LV DQ LQGLYLGXDO FDSDEOH RI GHOLEHUDWLRQ
GLUHFWRQ RI VXFK GHOLEHUDWLRQ 7R UHVSHFW DXWRQRP\ LV WR JLYH
RSLQLRQV DQG FKRLFHV ZKLOH UHIUDLQLQJ IURP REVWUXFWLQJ WKHLU D
RWKHUV 7R VKRZ ODFN RI UHVSHFW IRU DQ DXWRQRPRXV DJHQW LV WR U
MXG~~HO~~WV WR GHQ\ DQ LQGLYLGXDO WKH IUHHGRP WR DFW RQ WKRVH FRQ
LQIRUPDWLRQ QHFHVVDU\ WR PDNH D FRQVLGHUHG MXGJPHQW ZKHQ WKH

+RZHYHU QRW HYHU\ KXPDQ E~~HO~~UHV~~FO~~SD~~ERQ~~ 7KH~~HO~~SD~~ERQ~~WR~~ERQ~~HOI
VRPH LQGLYLGXDOV ORVH

SULVRQHUV WR YROXQWHHU RU WR SURWHFW WKHP SUHVHQWV D GLOH
RIWHQ D PDWWHU RI EDODQFLQJ FRPSHWLQJ FODLPV XUJHG E\ WKH SULQF

~~W~~QHILFHQEMRQV DUH WUHDWHG LQ DQ HWKLFDO PDQQHU QRW RQO

VXFK LQIOXHQFLQJ IDFWRUV H[LVWV KRZHYHU DQG LW LV LPSRVVLEOH W
HGGV DQG XQGXH LQIOXHQFH EHJLQV %XW XQGXH LQIOXHQFH ZRXOG LQF
SHUVRQ V FKRLFH WKURXJK WKH FRQWUROOLQJ LQIOXHQFH RI D FORVH U
VHUFLFHV WR ZKLFK DQ LQGLYLGXDO ZRXOG RWKHUZLVH EH HQWLWOHG

\$VVHVVP HQWQGI %HVHILWV VHVVP HQW RI ULVNV DQG EHQHILWV
FDUHIXO DUUDIDO RI UHOHYDQW GDWD LQFOXGLQJ LQ VRPH FDVHV DOW
WKH UHVHDFK 7KXV WKH DVVHVVP HQW SUHVHQWV ERWK DQ RSSRUWXQI
DQG FRPSUHKHQVLYH LQIRUPDWLRQ DERXW SURSRVHG UHVHDFK)RU WK
ZKHWKHU WKH SURSRVHG UHVHDFK LV SURSHUO\ GHVLJQHG)RU D UHYL
ZKHWKHU WKH ULVNV WKDW ZLOO EH SUHVHQWHG WR VXEMHFW DUH MXV
ZLOO DVVLVW WKH GHWHUPLQDWLRQ ZKHWKHU RU QRW WR SDUWLFLSDWH

The Nature and Scope of Risks and Benefits. 7KH UHTXLUHPHQW WKDW UHVHDFK EH MXV
IDYRUDEOH ULVN EHQHILW DVVHVVP HQW EHDUV D FORVH UHODWLRQ WR W
UHTXLUHPHQW WKDW LQIRUPHG FRQVHQW EH REWDLQHG LV GHULYHG SUL
7KH WHUP ULVN UHWHUWKDW D SURVVIDELDFXU +RZHYHU ZKHQ H[SUHVLR
RU KLJK ULVN DUH XVHG WKH\ XVXDOO\ UHWHU RIWHQ DPELJRXVO\ ER
H[SHULHQFLQJ D KDUP DQG WKH VHYHULW\ PDJQLWXGH RI WKH HQYLVL

7KH WHUP EHQHILW LV XVHG LQ WKH UHVHDFK FRQWH[W WR UHWHU WR
ZHUIDUH 8QOLNH ULVN EHQHILW LV QRW D WHUP WKDW H[SUHVHV S
SUREDELOLW\ RI EHQHILW DQG EHQHILW DUH SURSHUO\ FRQWUDVWHG
\$FFRUGLQJ DOOVR ULVN EHQHILW DVVHVVP HQW DUH FRQFHUQH ZLWK W
SRVVLEOH KDUP DQG DQWLFLSDWHG EHQHILW 0DQ\ NLQGVRV SRVVLEOH
DFFRXQW 7KHUH DUH IRU H[DP SOH ULVNV RI SV\FKRORJLFDO KDUP SK\V
HFRQRPLF KDUP DQG WKH FRUHVSRQGLQJ EHQHILW :KLOH WKH PRVW O
DUH WKRVH RI SV\FKRORJLFDO RU SK\VLFDQ SDLQ RU LQMXU\ RWKHU SRV

5LVNV DQG EHQHILWV RI UHVHDFK PD\ DIIHFW WKH LQGLYLGXDO VXEMHF
VRFLHW\ DW ODUJH RU VSHFLDO JURXS RI VXEMHFW LQ VRFLHW\ 3UH
UHTXLUHG WKDW ULVNV WR VXEMHFW EH RXWZHLJKHG E\ WKH VXP RI ER
DQG WKH DQWLFLSDWHG EHQHILW WR VRFLHW\ LQ WKH IRUP RI NQRZOHGJ
WKHVH GLIIHUHQW HOHPHQWV WKH ULVNV DQG EHQHILWV DIIHFWLQJ WKH
VSHFLDO ZHLJKW 2Q WKH RWKHU KDQG LQWHUHVWV RWKHU WKDQ WKRVH
VXIIILFLHQW E\ WKHPVHOYHV WRWKH UHVHDFK KULWNR OROJ DOYMKH LQXEMHFW
SURWHFWHG %HQHILFHQFH WKXV UHTXLUHV WKDW ZH SURWHFW DJDLQVW
FRQFHUQH DERXW WKH ORVV RI WKH VXEVWDQWLDO EHQHILWV WKDW PL

The Systematic Assessment of Risks and Benefits. ,W LV FRPPRQO\ VDLG WKDW EHQHILWV DQ
EDODQFHG DQG VKRZQ WR EH LQ D IDYRUDEOH UDWR 7KH PHWDSKRUI
DWWHQWLRQ WR WKH GLIILFXOW\ RI PDNLQJ SUHFLVH MXGJPHQWV 2QO\ R
DYDLODEOH IRU WKH VFUXWLQ\ RI UHVHDFK SURWRFROV +RZHYHU WKH
ULVNV DQG EHQHILWV VKRXOG EH HPXODWHG LQVRIDU DWLSDVDEORXW 7KLV
WKH MXVWLILDELOLW\ RI UHVHDFK WR EH WKURXJK LQ WKH DFFXPXODW
DVSHFWV RI WKH UHVHDFK DQG WR FRQVLGHU DOWHUQDWLYHV V\WHPD
RI UHVHDFK PRUH ULJRURXV DQG SUHFLVH ZKLOH PDNLQJ FRPPXQLFDWL
LQYHVWLJDWRUV OHVV VXEMHFW WR PLVLQWHUSUHWDWLRQ PLVLQIRUPDV
ILUVW EH D GHWHUPLQDWLRQ RI WKH YDOLGLW\ RI WKH SUHVXSSRVLWLRQ
PDJQLWXGH RI ULVN VKRXOG EH GLVWLQJXLVKHG ZLWK DV PXFK FODULW\
VKRXOG EH H[SOLFLW HVSHFLDOO\ ZKHUH WKHUH LV QR DOWHUQDWLYH W
VOLJKW ULVN ,W VKRXOG DOVR EH GHWHUPLQHG ZKHWKHU DQ LQYHVWLJD
EHQHILWV DUH UHDFRQDEOH DV MXGJHG E\ NQRZQ IDFV RU RWKHU DYD

)LQDOO\ DVVHVVP HQW RI WKH MXVWLILOHED\OWWWKH LRHOVDFZLFKJ VKRXOG UH
FRQVLGH (i) D%W XRVDO RU LQKXPDQH WUHDWPHQW RI KXP (D) G LAXNEW M KWXOLG/ QH
EH UHGXFHG WR WKRVH QHFHVVDU\ WR DFKLHYH WKH UHVHDUFK REMHFWD
IDFW QHFHX\WHDUKXWRQ VXEMHFWV DW DOO 5LVN FDQ SHUKDSV QHYHU EH H
EH UHGXFHG E\ FDUHIXO DWWHQW (ii) R: K HCR UHOMH D W G B W L Q Y H R S U R V H G X Q H M F D
VHULRXV LPSDLUPHQW UHYLHZ FRPPLWWHHV VKRXOG EH H[WUDRUGLQDUL
ORRNLQJ XVXDOO\ WR WKH OLNHORU R R G R R E H H Q D I U L W F D R H W K H W R X V M H F W D Q
DSSURSOLOD@HFC#V RI LQYROYLQJ WKHP VKRXOG LWVHOI EH GHPRQVWUDW

> @LQFH YDULRXV FRGHV IRU WKH SURSHU DQG UHVSQVLEOH FRQGXFWRU RI KXPDUH
DGRSWHG E\ GLIIHUHQW RUJDQLJDWLRQV 7KH EHVW NQRZQ RI WKH VH FRGHV DUH WKH 1X
UHVLVHG LQ DQG WKH *XLGHOLQHV FRGLLHG LQWR)HGHUO 5HJXODWLRQ
+HDWK (GXFDWLRQ DQG :HOIDUH &RGHV IRU WKH FRQGXFWRU RI VRFLDO DQG EHKDYLRU
EHLQJ WKDW RI WKH \$PHULFDQ 3V\FKRORJLFDQ \$VVRFLDWLRQ SXEOLVKHG LQ

> \$OWKRXJK SUDFWLFH XVXDOO\ LQYROYHV LQWHUYHQWLRQV GHVLJQHG VROHO\ WR HQK
DUH VRPHWLPHV DSSOLHG WR RQH LQGLYLGXDO IRU WKH HQKDQFHPHQW RI WKH ZHOE EH
WUDQVSDQWV RU DQ LQWHUYHQWLRQ PD\ KDYH WKH GXDO SXUSRVH RI HQKDQFLQJ WKH
WLPH SURYLGLQJ VRPH EHQHILW WR RWKHUV H J YDFFLQDWLRQ ZKLFK SURWHFWV ER
7KH IDFW WKDW VRPH IRUPV RI SUDFWLFH KDYH HOHPHQWV RWKHU WKDQ LPPHGLDWH EH
KRZHYHU VKRXOG QRW FRQIXVH WKH JHQHUDO GLVWLQFWLRQ EHWZHHQ UHVHDFK DQG
EHQHILW VRPH RWKHU SHUVRQ LW UHPDLQV DQ LQWHUYHQWLRQ GHVLJQHG WR HQKDQFH
LQGLYLGXDOV WKXV LW LV SUDFWLFH DQG QHHG QRW EH UHVLVHG DV UHVHDFK

> %HFDXVH WKH SUREOHPV UHODWHG WR VRFLDO H[SHULPHQWDWLRQ PD\ GLIIHU VXEVWD
UHVHDFK WKH &RPLVVLRQ VSHFLILFDQO\ GHFOLQHV WR PDNH DQ\ SROLF\ GHWHUPLQ
&RPLVVLRQ EHOHYHV WKDW WKH SUREOHP RXJKW WR EH DGGUHVHG E\ RQH RI LWV V