

# 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

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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 %LRPHG  
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\RWPHQW &RQGLULHV EHWZHHQ ELRPHGLFDO DQG EHKDYLRUDO UHVH  
SUDFWLFH R(ii)MICHLELOH RI DVVHVPHQW IRU LWLVNLD LQ WKH GHWHUPLQDWLRQ  
UHVHDFK LQYROYLQJ DSSUR SULDWH JXLGHOLQHV IRU WKH VHOHFWLRQ RI KXP  
VXFK UHVHDFK QDWXUH DQG GHILQLWLRQ RI LQIRUPHG FRQVHQW 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 VSKALVFOURRQPHSHQSDWLG  
DGPLQLVWUDWLYH DFWLRQ E\ WKH 6HFUHWDU\ RI +HDOWK (GXFDWLRQ DQG :H  
WKH %HOPRQW 5HSRUW EH DGRSWHG LQ LWV HQWLUHW\ DV D VWDWHPHQW RI  
SXEOLF FRPPHQW RQ WKLV UHFRPPHQGDWLRQ

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1DWLRQDO &RPPLVVLRQ IRU WKH 3URWHFWLI  
%LRPHGLFDO DQG %HKDYLRUDO 5HVHDUFK  
0HPEHUV RI WKH &RPPLVVLRQ

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'HFHDVHG

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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  
\$VVHVPHQW RI 5LVN DQG %HQHILWV  
6HOHFWLRQ RI 6XEMHFWV

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## (WKLFDO 3ULQFLSOHV \*XLGHOLQHV IRU 5HVHDFK

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

7KH FRGHV FRQVLVW RI UXOHV VRRPH JHQHUDO RWKHUV VSHFLILF WKDW UHVHDFK LQ WKHLU ZRUN 6XFK UXOHV RIWHQ DUH LQDGHTXDWH WRFRYFRQIOLFW DQG WKH\ DUH IUHTXHQWO\ GLIILFXOW 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 WKH LQVHQVHG DQVXVHMLQVHW SULQFLSOHV FDQQRW DOZD\V EH DSSOLHG VR DV WR UHVROYH EH\RQG GLREMHWLYH LV WR SURYLGH DQ DQDO\WLFDO IUDPHZRUN WKDW ZLOO JXLGH UHVHDFK LQYROYLQJ KXPDQV XEMHFWV

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

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## 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 KXPDQV XEMHFWV 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 REMHWLYH DQG D VHW RI SURFHGXUHV

:KHQ D FOLQLFLDQ GHSDUWV LQ D VLJQLILFDQW ZD\ IURP VWDQGDUG RU D DQG RI LWVHOI FRQVLWXWH UHVHDFK 7KH IDFW WKDW D SURFHGXUHV RI 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

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## 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 LQWHUWVWLWV  
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 FRQVLGHUHGX MXGJPHQW ZKHQ WKH

+RZHYHU QRW HYHU\ KXPDQ E~~HO~~WV LQSDWLRQ 7KH GHOSDFLOWREHQ\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  
VHUYLEFHV WR ZKLFK DQ LQGLYLGXDO ZRXOG RWKHUZLVH EH HQWLWOHG

**\$VVHVVP HQWQGI %HVHILWV** VHVVP HQW RI ULNVV DQG EHQHILWV  
FDUHIXO DUUDIDO RI UHOHYDQW GDWD LQFOXGLQJ LQ VRPH FDVHV DOW  
WKH UHVHDFK 7KXV WKH DVVHVVP HQW SUHVHQWV ERWK DQ RSSRUWXQ  
DQG FRPSUHKHQVLYH LQIRUPDWLRQ DERXW SURSRVHG UHVHDFK )RU WK  
ZKHWKHU WKH SURSRVHG UHVHDFK LV SURSHUO\ GHVLJQHG )RU D UHYL  
ZKHWKHU WKH ULNVV WKDW ZLOO EH SUHVHQWHG WR VXEMHFWV 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\ UHIHU 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 UHIHU 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 HQWV DUH FRQFHUQHG ZLWK W  
SRVVLEOH KDUP DQG DQWLFLSDWHG EHQHILW 0DQ\ NLQGVRV SRVVLEOH  
DFFRXQW 7KHUH DUH IRU H[DP SOH ULNVV 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 VXEMHFWV LQ VRFLHW\ 3UH  
UHTXLUHG WKDW ULNVV WR VXEMHFWV EH RXWZHLJKHG E\ WKH VXP RI ER  
DQG WKH DQWLFLSDWHG EHQHILW WR VRFLHW\ LQ WKH IRUP RI NQRZOHGJ  
WKHVH GLIIHUHQW HOHPHQWV WKH ULNVV DQG EHQHILWV DIIHFWLQJ WKH  
VSHFLDO ZHLJKW 2Q WKH RWKHU KDQG LQWHUHVWV RWKHU WKDQ WKRVH  
VXIIILFLHQW E\ WKHPVHOYHV WRWKH UHVHDFK KULNORQJ DOYMGHLQXEMHFW  
SURWHFWHG %HQHILFHQFH WKXV UHTXLUHV WKDW ZH SURWHFW DJDLQVW  
FRQFHUQHG 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  
ULNVV DQG EHQHILWV VKRXOG EH HPXODWHG LQVRIDU DWL&RQVDE&XW7KLV  
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 IDFVV 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 LAXNEWM N KW XOLG/ QH  
EH UHGXFHG WR WKRVH QHFHVVDU\ WR DFKLHYH WKH UHVHDUFK REMHFWL  
IDFW QHFHX\WHD UKX WBRQ VXEMHFWV DW DOO 5LVN FDQ SHUKDSV QHYHU EH H  
EH UHGXFHG E\ FDUHIXO DWWHQW(ii) R: K HCR UHOMH DUC B W LQYR SURV HGLX QHM FD  
VHULRXV LPSDLUPHQW UHYLHZ FRPPLWWHHV VKRXOG EH H[WUDRUGLQDUL  
ORRNLQJ XVXDOO\ WR WKH OLNHORU RRG RR FEH QIDULW FDR HWKHWRXV M H FV D Q  
DSSURSOLODV@HFC#V RI LQYROYLQJ WKHP VKRXOG LWVHOI EH GHPRQVWUDW

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> @LQFH YDULRXV FRGHV IRU WKH SURSHU DQG UHVSQVLEOH FRQGXFWRU RI KXPDUH  
DGRSWHG E\ GLIIHUHQW RUJDQLJDWLRQV 7KH EHVW NQRZQ RI WKHVH 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