

## Procedure 1350 PR.01 Human Embryonic Stem Cell Research

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### Purpose

The purpose of these procedures is to provide guidance for all faculty, staff, and students who are conducting research on human embryonic stem cell (hESC) lines or have financial responsibility for the funding that supports the research. The policy for conducting hESC research is located on the [Provost website](#).

These hESC procedures, which must be observed by all persons at the University, including faculty, staff, postdoctoral scholars, students, visiting scholars and other researchers, have been developed in part to ensure that all non-federally approved research involving non-registered hESC lines is conducted in such a manner as to preclude any inappropriate use of federal funds, directly or indirectly. In addition to these procedures, non-federal sponsors such as the Connecticut Stem Cell Research Fund (CSCRF) may impose special terms and conditions which must be followed.

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### Operating Procedures

1. All hESC research must meet the following requirements:
  - a. Approval by the Embryonic Stem Cell Research Oversight (ESCRO) Committee.
  - b. Investigators using hESC must fulfill the ESCRO training requirement as prescribed by the [Provost's Office](#).
  - c. A full review of University compliance by the Grant and Contract Administration (GCA) office. This review verifies compliance with University policies on ESCRO, human investigation (HIC), animal care and use (IACUC), conflict of interest (COI), personnel effort, location of research activity, and funding sources (including cost sharing).
2. All research on hESC lines that are not registered in the National Institutes of Health (NIH) [stem cell registry](#) is also subject to the following additional procedures:
  - a. A full review of allocation methodologies by the Stem Cell Research Resource Allocation Protocol (SCRRAP) Committee. This review is initiated by the Principal Investigator's (PI) completion of the [Human Embryonic Stem Cell Research Tracking](#) (HESCRT) form. The SCRRAP Committee certifies compliance with Federal, State, and University policies on the use of facilities, personnel, equipment, materials and supplies for hESC research on non-registered lines.
  - b. A cost allocation process that segregates all of the costs related to the non-registered hESC research and has the approval of the SCRRAP Committee.
  - c. Fulfillment of the SCRRAP Committee training requirement for all investigators involved in the non-registered hESC research and all financial staff from the investigator's business office.

## Allocation of Costs

Allocation is defined as the process of assigning a cost, or a group of costs, to a project or sponsored agreement in a reasonable and realistic proportion to the benefit provided or other equitable relationship.

Costs related to non-registered hESC lines must be allocated to non-federal funding sources only. Review University [Guide 1305 GD.07 Determining Allowability, Reasonableness, and Allocability of Costs for Sponsored Projects](#) for additional information regarding allocation methodologies. Researchers conducting non-registered hESC research and receiving both federal and non-federal funding must allocate their costs as follows:

**Personnel Effort:** The University's existing policies for tracking, allocating and confirming effort on sponsored projects for all personnel must be used to ensure that effort devoted to non-registered hESC research is not paid with federal funds. In addition, for individuals who are conducting non-registered hESC research and are supported with departmental funds, that effort should be tracked to the non-registered hESC research project and linked to the departmental funds award in a manner similar to setting up a cost sharing account. Refer to [Procedure 1306 PR.01 Cost Sharing](#). Certification of effort devoted to a sponsored project is through the University's effort reporting process. Salary must be allocated and charged to the non-federal accounts commensurate with the effort devoted to the non-registered hESC project(s).

Review University [Policy 1315: Effort Reporting: Certifying Effort on Sponsored Projects](#) and [Policy 1316: Effort Commitments: Managing Effort Associated with Sponsored Projects](#) for more information regarding reporting effort.

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## Special Operating Procedures

**Facilities:** Yale facilities, on or off campus, may be used to conduct non-registered hESC research if the following conditions apply:

1. The building facilities used for the research are identified for use on the [HESCRT form](#) (see Form 1350 FR.01); and
2. The HESCRT form has been approved by the SCRRAP Committee and the PI has received written approval to use the facility.

Note: Federal space, such as the Veterans Administration facility, may not be used in the conduct of non-registered hESC research.

**Equipment:** Equipment is subject to review by the SCRRAP Committee to determine title and the appropriate use of the equipment if the following conditions apply:

1. The purchase price was greater than \$5,000 (greater than \$2,000 if purchased prior to July 1, 2006);
2. The useful life is more than one year; and
3. The equipment is located in a laboratory where personnel are conducting hESC research.

After the careful review of each piece of equipment with the PI, the SCRRAP Committee will label the equipment according to the following criteria:

- a. **Equipment Owned by the Federal Government:** Equipment that is owned by the federal government (purchased with federal funds and the title remains with the federal government) may not be used in conducting non-registered hESC research. Federally owned equipment must be tagged with a red **DO NOT USE ON NON-REGISTERED HUMAN ESC LINES** tag to ensure that it is not used for non-registered hESC research.
- b. **Equipment Purchased by the University with Federal Funds:** Equipment purchased with federal funds may not be used for conducting non-registered hESC research unless it meets one of the following criteria:
  - 1) The award period for the federal funding that was used to purchase the equipment has ended and the University retains the title to the equipment without restrictions; or
  - 2) The University purchases the equipment, obtains the title without restrictions, and has documentation of the transaction.

This equipment will be reviewed on a case-by-case basis by the SCRRAP Committee. Equipment that meets one of these criteria must be tagged with a blue **APPROVED FOR USE ON NON-REGISTERED HUMAN ESC LINES** tag.

- c. **Equipment Owned by the University:** Equipment that is owned by the University and has not been purchased with any federal funds and is not subject to any other funding restrictions may be used for non-registered hESC research. This equipment must be tagged with a blue **APPROVED FOR USE ON NON-REGISTERED HUMAN ESC LINES** tag prior to use on non-registered lines.

Equipment lists generated by Grant and Contract Financial Administration (GCFA) and categorized by SCRRAP will be reviewed with the PIs. The PIs will verify the accuracy of the lists of approved and unapproved equipment. The PIs will also certify that the equipment will be used appropriately.

Laboratories where non-registered hESC research is being conducted will be subject to periodic inventories (no less than annually) by the Yale Stem Cell Center (YSCC) to ensure that the equipment is tagged properly and is being used appropriately.

**Expendable Laboratory Materials and Supplies:** The procurement and/or current inventory of laboratory materials and supplies used for non-registered hESC research must be purchased with non-federal funds. These materials and supplies must be stored in a physical location separate from the other laboratory materials and supplies. If materials and supplies purchased with federal funds will be used in the same physical location as materials and supplies being used for research on non-registered lines, the PI will develop a written plan to ensure that the federally purchased materials and supplies will not be used for non-registered research. The plan must receive the prior approval of the SCRRAP Committee and will be monitored periodically by the YSCC.

## **Data and Other Intellectual Property**

The federal government may not be charged for generating data from non-registered hESC research; therefore, the PI must consult with the SCRRAP Committee before using any University internal service providers such as the Keck Biotechnology Facility for generating or analyzing non-registered hESC data.

The University is free to license materials or inventions developed through non-federally funded hESC research, subject to University policies and any third-party restrictions.

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## **Non-federal Sponsor Compliance, Financial Monitoring and Reporting**

### **Compliance**

The department business office shall retain full, accurate and current receipts, vouchers, and financial records regarding projects supported by non-federal sponsors such as the CSCRF. The documents will be stored during the term of the award in accordance with the University's policy on [record retention](#).

Non-federal sponsors may have the right to inspect and audit the minutes, records, books, files, documents, payroll, employment conditions, contracts and any and all other papers of the PI upon reasonable notice. All notifications of a review/audit must be brought to the immediate attention of SCRRAP and the Associate Vice President for Research and Compliance.

The department business office shall also maintain full, accurate and current receipts, vouchers, and financial records regarding hESC research supported by discretionary funding.

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### **Monitoring**

PIs funded by non-federal sponsors such as the CSCRF will be expected to participate in periodic reviews by the Yale University Audit Department and the University Research Compliance Officer to ensure that all applicable regulations are being followed, and to evaluate the effectiveness of the University policies and procedures related to the conduct of hESC research.

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### **Reporting**

Research projects funded by non-federal sponsors such as the CSCRF must follow the reporting requirements of the award.

Responsible Person(s)	Description of Responsibilities
<p><b>ESCRO</b></p>	<p>In order to ensure adherence to ethical and legal principles of hESC research, the University has established an Embryonic Stem Cell Research Oversight (ESCRO) Committee along the lines of recommendations by the National Research Council and Institute of Medicine of the National Academies' 2005 Guidelines for hESC research. ESCRO members are appointed by and serve as advisors to the Office of the Provost. The membership of the ESCRO reflects the scientific, medical, and ethical expertise necessary to perform the responsibilities described below, and includes members of the University community (faculty, staff and/or students), as well as outside members, at the election of the Provost.</p> <p>The ESCRO is responsible for:</p> <ul style="list-style-type: none"> <li>• Providing scientific, medical and ethical review of proposed hESC research, regardless of whether the proposed research also requires consideration by an IRB;</li> <li>• Providing a focal point for campus consideration of all issues related to derivation and research use of hESC lines;</li> <li>• Facilitating education of investigators in the ethical, legal, and policy issues involved in hESC research, including setting minimum educational requirements as prerequisites for conducting hESC research;</li> <li>• Assisting investigators in assessing which regulations apply to proposed hESC research activities;</li> <li>• Ensuring that the provenance of hESCs is documented and that there was IRB approval of the procurement process in order to ensure adherence to the basic ethical and legal principles of informed consent and protection of confidentiality;</li> <li>• Establishing and maintaining a registry of the University hESC research, including documentation of key personnel, descriptive information about the types of research being performed, and the hESCs in use;</li> <li>• Reviewing evolving regulations and guidance and making recommendations to update University policy "<a href="#">Review of Human Embryonic Stem Cell Research</a>"; and</li> <li>• Ensuring that all applicable hESC regulatory requirements are met and that hESC research is conducted in accordance with the highest ethical standards.</li> </ul>
<p><b>Principal Investigator</b></p>	<p>The PI has overall responsibility for compliance with all terms and conditions of the sponsored award. In particular, the PI must ensure that federal funds are not used, directly or indirectly, to support research on non-registered hESC lines. The PI's responsibilities include but are not limited to:</p> <ul style="list-style-type: none"> <li>• Obtaining all required committee approvals (ESCRO, SCRRAP, IACUC, HIC, COI, etc.);</li> <li>• Completing the required training and ensuring all research and administrative personnel involved with hESC awards complete the required training;</li> <li>• Informing research and administrative personnel of the SCRRAP-approved procedures for assigning costs to hESC research projects;</li> <li>• Ensuring appropriate costs are charged to hESC awards by regularly reviewing financial reports; and</li> <li>• Preparing and submitting timely progress reports in the required format and timeframes prescribed by the sponsored agreement.</li> <li>• Complying with University policies supporting the management and administration of grants and contracts.</li> </ul>

Responsible Person(s)	Description of Responsibilities
<p><b>SCRRAP Committee</b></p>	<p>In order to ensure adherence to the resource allocation protocols for the use of non-registered hESC lines, the University has established the Stem Cell Research Resource Allocation Protocol (SCRRAP) Committee. The SCRRAP Committee is comprised of members of the School of Medicine's Finance Office, GCA, General Counsel's Office, Office of Research Administration, and the YSCC.</p> <p>The SCRRAP Committee is responsible for:</p> <ul style="list-style-type: none"> <li>• Ensuring that federal funds are not used, directly or indirectly, to support research on non-registered hESC lines and the provisions of <a href="#">OMB Circular A-110</a>, <a href="#">A-21</a>, and the Federal Demonstration Partnership terms and conditions are followed;</li> <li>• Providing financial review and approval of methodologies used to identify, track, calculate, and report on allocation of expenses used to support research on non-registered hESC lines, including expenses for supplies and personnel;</li> <li>• Identifying and documenting facilities and equipment that were purchased with federal funds and determining whether they may be used for research on non-registered hESC lines;</li> <li>• Ensuring that laboratory equipment is labeled with appropriate equipment tags;</li> <li>• Providing on-site evaluations of laboratory space and equipment of investigators interested in performing research studies on non-registered hESC lines;</li> <li>• Reviewing and approving requests and cost allocation methodologies of the effort of personnel to engage in hESC research; and</li> <li>• Providing guidance and answering questions regarding the hESC research cost allocation procedures.</li> </ul>
<p><b>Department Administrator</b></p>	<p>The Department Administrator is responsible for assisting the PI to ensure that federal funds are not used, directly or indirectly, to support research on non-registered hESC lines. Department Administrators who administer awards that support registered and non-registered hESC research are responsible for:</p> <ul style="list-style-type: none"> <li>• Ensuring that the PIs have an approved application from the ESCRO prior to incurring expenses;</li> <li>• Ensuring that the PIs have an approved HESCRT form from the SCRRAP prior to commencement of the research;</li> <li>• Ensuring that the PI's laboratory and all financial members of the Business Office have completed the hESC training;</li> <li>• Implementing cost allocation methods approved by the SCRRAP Committee to ensure the proper allocation of costs to the appropriate funding sources;</li> <li>• Providing financial reports to the PI for review and making any necessary financial adjustments;</li> <li>• Complying with University policies relating to the administration and management of grants and contracts;</li> <li>• Providing the Account Holder reports to PIs supported by non-federal awards; and</li> <li>• Alerting the SCRRAP to any changes in the facilities, equipment, or personnel involved in non-registered hESC research.</li> </ul>

Responsible Person(s)	Description of Responsibilities
<b>GCA</b>	<p>The GCA is responsible for ensuring that all policies and procedures related to hESC research at the University are followed. They are responsible for:</p> <ul style="list-style-type: none"> <li>• Reviewing all hESC funding applications to ensure compliance with University policies on ESCRO, HIC, IACUC, COI, and SCRRAP;</li> <li>• Notifying the SCRRAP Committee of proposals to use hESC and requests for hESC lines via a Material Transfer Agreement;</li> <li>• Approving licensing of materials or inventions developed through federally or non-federally funded hESC research; and</li> <li>• Resolving issues that result from inadvertent charges of hESC research to federal funds.</li> </ul>
<b>YSCC Administrator</b>	<p>In order to ensure adherence to the resource allocation protocols and to assist with the financial administration of Connecticut stem cell research funding using hESC lines, the YSCC has appointed an Administrator.</p> <p>The YSCC Administrator is responsible for:</p> <ul style="list-style-type: none"> <li>• Assisting PIs and business office staff with developing methodologies to identify, track, calculate, and report on allocation of expenses used to support research on non-registered hESC lines;</li> <li>• Collecting and reviewing all expenses related to CSCR award to ensure the appropriate use of funds;</li> <li>• Conducting regular reviews of research laboratories to ensure compliance with the procedures for cost allocation of personnel, materials, supplies, and equipment; and</li> <li>• Providing reports to funding agencies that have supported hESC research</li> </ul>
<b>GCFA</b>	<p>The GCFA is responsible for post-award compliance for all sponsored awards. This Office is responsible for:</p> <ul style="list-style-type: none"> <li>• Financial reporting on sponsored project awards;</li> <li>• Providing accounts receivable functions for sponsored projects: invoicing, recording receipts, collections;</li> <li>• Subrecipient monitoring;</li> <li>• Cost transfer review and approval;</li> <li>• Management of other sponsored project compliance issues including sponsor requests for audits;</li> <li>• Annual A-133 Audit reports including State of Connecticut Single Audit Report; and</li> <li>• Effort reporting</li> </ul>

## Related Information

[Policy 1306](#): Cost Sharing on Sponsored Projects

[Policy 1315](#): Effort Reporting: Certifying Effort on Sponsored Projects

[Policy 1316](#): Effort Commitments: Managing Effort Associated with Sponsored Projects

[Policy 1105](#): Retention of University Financial Records

[Procedure 1306 PR.01](#): Cost Sharing

[Provost's hESC Policy](#)

[ESCRO Committee](#)

## Contacts

The following individuals are available to provide support and answer questions.

Subject	Contact	Phone
ESCRO Committee	Dr. Sandra Alfano	785-4688
SCRRAP Committee	Paula Wilson	785-5658
GCA	Penny Cook	785-6475
GCFA	Dennis Titley	432-3074
Research Compliance	Alice Tangredi-Hannon	432-8796
General Counsel	Robert Bienstock	432-4949

## Frequently Asked Questions

The following questions and answers are for the benefit of University personnel involved in research on non-registered hESC lines that are ineligible for federal funding. Please check these procedures periodically for updates that could result from changes in federal, sponsor, or University policies and procedures.

### A. PERSONNEL

**1. What factors determine how much time researchers can devote to non-registered hESC research?**

In accordance with University policy and federal requirements, the total allowable amount of an individual's committed effort cannot exceed 100%. Researchers can commit effort to non-registered hESC research provided their effort allocated to all University activities, including federally and non-federally funded projects, teaching and administrative responsibilities, clinical duties, and other projects and commitments is adjusted so that the total is 100% and does not conflict with other commitments. Refer to Policy 1316.

**2. How does the PI ensure that researchers are staying within the bounds of the maximum work effort they are permitted to commit to non-registered hESC research?**

Researchers must comply with the University's policy regarding commitment of effort not only for non-registered hESC research, but effort devoted to other sponsored projects. For researchers who are conducting non-registered hESC research and are supported with departmental funds, that effort should be tracked to the non-registered hESC research project and linked to the departmental funds award in a manner similar to setting up a cost sharing account.

**3. A PI committed to devoting 50% of his/her time on a federally-funded project would like to devote 75% of his/her time working on non-registered hESC research. Can s/he be accommodated?**

To the extent that a reduction in a researcher's commitment to the federally-funded project can be negotiated with the sponsor, an individual may spend the balance of his/her time on non-registered hESC research, taking into account the researcher's other commitments and teaching or administrative responsibilities.

**4. A researcher who works on both non-registered and registered hESC lines would like to attend a conference on stem cell research. Can s/he charge the costs of his/her attendance to federal funding sources?**

The costs of activities undertaken for the benefit of both non-registered and registered hESC research should be allocated in proportion to the benefit that each award would receive. Therefore, if the conference addresses topics that relate to both non-registered and registered hESC research, a researcher who spends 75% of his/her total hESC research time working on non-registered lines and

25% working on registered lines may charge some of the costs of attending the conference to a federal funding source, only if the allocation methodology has been approved by the SCRRAP prior to the trip.

**5. A researcher who works on both non-registered and federally-funded hESC lines is presenting a paper describing the findings of his/her non-registered stem cell research at a conference. Can s/he charge the costs of his/her attendance to federal funding sources?**

If the researcher is attending the conference solely to present the findings of non-registered hESC research, s/he may not charge any portion of the costs of attendance to federal funding sources.

**6. Can students supported by federal funding also work on non-registered hESC research projects?**

Yes, subject to the general protocols governing personnel work effort and if they have sufficient time to devote to the research and not compromise the 20-hours per week requirement. The extent to which students will be able to engage in hESC research will depend on what work terms, if any, are contained in their funding agreements. The administrative procedures apply only to persons who work on non-registered hESC research projects, and not, for example, students in a class in which non-registered hESC research is discussed as part of an academic program.

**B. FACILITIES**

**7. Can researchers who receive federal funding also use their laboratories to conduct non-registered hESC research?**

With SCRRAP Committee prior approval, researchers who receive federal funding may also use their laboratories to conduct non-registered hESC research. They must, however, monitor effort, and physically separate materials and commodities, purchased services, and, in some cases, equipment usage, associated with non-registered hESC research in order to allow for allocation of costs between registered and non-registered activities.

**8. Can the investigator outsource services for non-registered stem cell research to internal service providers at the University such as the Keck Biotechnology Facility?**

Yes, but with prior approval from the SCRRAP Committee. With respect to the University internal service providers, (1) there must be no restrictions on using the services for non-registered hESC research, and (2) if the facilities are also used for federally funded projects, the researchers must follow an allocation methodology to keep the costs of registered and non-registered activities separate.

**C. EQUIPMENT**

**9. Can researchers use equipment that has been approved by SCRRAP to conduct non-registered hESC research for a project that has federal funding?**

Yes, equipment that has been approved for use in non-registered hESC research can also be used for other federally-funded projects.

**10. Can researchers use equipment originally acquired to support a federal project to conduct non-registered hESC research?**

Maybe, depending on the source of funding used to purchase the equipment and who holds the title to the equipment. To use equipment for non-registered hESC research, researchers must seek prior approval from the SCRRAP Committee who will employ the following guidelines to permit use of the equipment.

- If the University holds title to the equipment, and no federal funds were used to acquire it, then researchers may use the equipment without restriction.
- If the University holds title to the equipment, but some federal funds were used to acquire it, then the equipment may not be used for non-registered hESC research unless it meets one of the following criteria:
  - The federal project has been completed and the University retains title to the equipment without restriction, allowing for any preference to federal usage.
  - The University has purchased the equipment from the federal government in full, without restriction, and has documentation of such transaction.

- GCA obtains, and the University confirms in writing, the approval of the appropriate federal agency, which may in some cases involve a rental agreement with the federal agency.

#### **D. MATERIALS, SUPPLIES, DURABLE GOODS, AND PURCHASED SERVICES**

##### **11. Can the University use materials and supplies purchased for general laboratory use to conduct non-registered hESC research?**

Yes, if they were purchased with non-federal funds, and if allocation and reimbursement methods ensure that the federal government pays no more than its share of the total materials and commodities costs. Allocation methods must be approved by SCRRAP. In the case of reusable goods that may be used on more than one project, the allocation plan must be particularly precise to ensure that there is no risk of over-allocation to the federal government.

##### **12. Can the University use purchased services for general laboratory use to conduct non-registered hESC research?**

Yes, researchers may use the services of consultants, laborers, maintenance/repair technicians, and other similar services for non-registered hESC research. As noted above, however, researchers must keep account of the portion of the purchased services used for federally funded projects so that the federal government pays no more than its share of the total costs of purchased services.

##### **13. Can the University use materials made available by the government at no cost, such as cell lines carrying particular diseases, for non-registered stem cell research?**

Yes, provided there are no applicable restrictions in the award of the materials, researchers are free to use materials provided at no cost for non-registered hESC research projects.

#### **E. DATA AND OTHER INTELLECTUAL PROPERTY**

##### **14. Can researchers use and/or analyze data and information generated from non-registered hESC research in federally-funded projects?**

Yes, but subject to any applicable restrictions on data usage imposed by other universities or research institutions, funding agencies, or other third parties. The federal government may not be charged for generating data from non-registered hESC research.

##### **15. Can researchers use data obtained from federally-funded projects in non-registered hESC research?**

Yes, but subject to any applicable restrictions on data usage imposed by other universities or research institutions, funding agencies, or other third parties. The federal government may not be charged for the costs of analyzing data for use in non-registered hESC research.

##### **16. Can the University license materials or inventions developed through non-federally-funded hESC research?**

Yes, the University is free to license materials or inventions developed through non-federally funded hESC research, subject to University policies and any third-party restrictions. The Office of Cooperative Research (OCR), in consultation with GCA, must be consulted before such licensing is approved.

##### **17. Can the University license materials or inventions developed through registered hESC research?**

Yes, subject to University policies and the terms of the federal award. OCR must consult with GCA before such licensing is approved.

#### **F. TROUBLESHOOTING**

##### **18. It has come to your attention that a PI has inadvertently failed to comply with the protocols and some of the costs of non-registered hESC research have been charged to federal funding sources. What should you do?**

If it comes to your attention that the federal government has been charged for some portion of the costs associated with non-registered stem cell research, contact the YSCC Administrator.

##### **19. Do researchers need additional approvals whenever there is a change in resource usage, including personnel, equipment, and facilities, associated with non-registered hESC research?**

To ensure that the federal government is not charged for non-registered hESC research, the SCRRAP Committee must review and approve such changes. Because resource usage is expected to change over time, researchers and administrators should arrange for usage approvals that can cover reasonably foreseeable fluctuations in resource needs.

**20. A researcher has a question about non-registered hESC research that is not answered by either the University policy "[Review of Human Embryonic Stem Cell Research](#)" or these procedures. Whom should the researcher contact for clarification?**

All questions on hESC that have not been answered in the policies and procedures should be directed either to the YSCC Administrator or GCA.

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The official version of this information will only be maintained in an on-line web format. Any and all printed copies of this material are dated as of the print date. Please make certain to review the material on-line prior to placing reliance on a dated printed version.

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